01-04-01 GP/1652

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Harrington *et al.*
Serial No.: Re. 09/586,744 Group No.: 1652
Filed: 06/02/00 Examiner: T. Saidha
Entitled: **MAMMALIAN FLAP-SPECIFIC ENDONUCLEASE**

PROTEST

#6 GP 1/16/01

Assistant Commissioner for Patents
Washington, D.C. 20231

ATTN: Jasemine Chambers
Group Art Unit: 1650

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.10

I hereby certify that this correspondence (along with any referred to as being attached or enclosed) are being deposisted with the U.S. Postal Service on **January 3, 2001** in an envelope as "EXPRESS MAIL POST OFFICE TO ADDRESSEE" service under 37 C.F.R. § 1.10, Express Mail Label Number **EL 658 777 744 US** addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, ATTN: Jasmine Chambers.

By: Susan M. McClintock

REMARKS

This is a Protest for application no. Re. 09/586,744, filed 06/02/00. Third Party Protestors believe no fee is required but if the Commissioner deems otherwise he is authorized to charge Deposit Accout No. 08-1290.

A copy of this Protest is also being forwarded on this day to counsel of record: Pennie & Edmonds, ATTN: Samuel B. Abrams, 1155 Avenue of the Americas, New York, NY 10036 in an envelope as "Express Mail Post Office to Addressee" service under 37 C.F.R. 1.10, Express Mail Label No. EK 898 390 565 US.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Harrington *et al.*
Serial No.: Re. 09/586,744 Group No.: 1652
Filed: 06/02/00 Examiner: T. Saidha
Entitled: **MAMMALIAN FLAP-SPECIFIC ENDONUCLEASE**

REISSUE APPLICATION PROTEST UNDER 37 C.F.R. 1.291

Assistant Commissioner for Patents
Washington, D.C. 20231

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.10

I hereby certify that this correspondence (along with any referred to as being attached or enclosed) are being deposited with the U.S. Postal Service in an envelope as "EXPRESS MAIL POST OFFICE TO ADDRESSEE" service under 37 C.F.R. 1.10, Express Mail Label No. EL 658 777 744 US addressed to Assistant Commissioner for Patents, Washington, D.C. 20231, ATTN: Jasmine Chambers.

Dated: January 3, 2001 By: Susan M. McClintock
Susan M. McClintock

Sir:

The following communication is presented to protest reissue application 09/586,744. This reissue application should be denied for the reasons stated below.

REMARKS

The present case represents an unprecedented abuse of the reissue process. The newly presented reissue claims are for a wholly different invention than the originally patented claims. These newly presented reissue claims will require the Examiner to conduct a *de novo* examination of the case. However, the Examiner need not conduct a substantive examination of the new claims because this reissue application fails to meet the basic procedural requirements of the reissue statute and can be denied on this basis.

First, no proper "error" as required for the reissue process has been identified or alleged (MPEP 1402). Applicants elected composition claims (*without traverse*) in the face

of a restriction requirement,[1] without ever pursuing the non-elected claims or other inventions in a divisional or continuation, thereby giving up such claims. Under controlling case law, this was a *choice*, not an error warranting reissue. Moreover, the six issued claims are re-presented in the reissue *without change*. This confirms there was no "error" in the issued claims warranting reissue.

Second, the new claims are directed to separate and distinct subject matter that is clearly not the "same invention" as required for a reissue (MPEP 1412.01). Indeed, the sixty-seven (67) new claims that have been added by amendment are all directed to alleged inventions that the inventors admit in sworn declarations they had not conceived of at the time the original application was filed. None of the new claims mention the subject matter of the original six issued claims. Thus, the reissue is not for the purpose of broadening or narrowing "the claims" as required by the statute (35 U.S.C. 251).

Third, all of the claims now sought to be added are drafted more broadly than the original six claims in an attempt by the new patent owner[2] to improperly recapture what was surrendered during the prosecution of the application (MPEP 1412.02), during which the claims were rejected and narrowed (*e.g.*, by virtue of the addition of "consisting" language) to overcome the Examiner's rejections. Having surrendered the broader claims, applicants cannot now use the reissue process to resurrect this subject matter.

Fourth, all sixty-seven added claims are unsupported by the original specification. To cover this deficiency, there has been an improper attempt to bodily incorporate the contents of a non-patent document (referenced in passing in the original specification) to provide support essential for the new claims. However, even with such an improper amendment of the specification (MPEP 1411.02), careful review of the claims reveals that all of the claims are *still unsupported*. The new claims have been pieced together in hindsight with no basis in the original specification or expanded specification for the claimed subject matter or claim terms now used.

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[1] The original six claims which issued are composition claims directed to nucleic acids encoding specific eukaryotic FEN-1 enzymes of particular sequences (defined by sequence ID numbers).

[2] The patent was sold to new owners (PE Corporation) on November 12, 1999 (*See*, Applicants' Certification Under 37 CFR 3.73(b) filed with this reissue application). This reissue application is clearly an attempt by the new owners to "mine" the patent for unrelated inventions.

FACTS

The following facts are relevant to present reissue application and this protest:

1) The original patent (U.S. Patent No. 5,874,283, hereinafter "the '283 patent"), entitled "Mammalian Flap-Specific Endonuclease", filed May 30, 1995, was previously owned by the inventors Harrington *et al.*

2) The '283 patent issued February 23, 1999.

3) On November 12, 1999, the inventors sold the patent to PE Corporation.

4) Several months after acquiring the patent, PE Corporation filed the present reissue application containing the originally patented Claims 1-6, and new Claims 7-73.

5) Claims 1-6 of the reissue application are unchanged from the originally patented Claims 1-6.

6) New claims 7-73, added by PE Corporation, are directed to different statutory subject matter than the originally patented Claims 1-6 (Claims 7-50 relate to diagnostic methods involving cleavage of specific cleavage structures; Claims 51-58 relate to hybridization complexes comprising a specific cleavage structure; and Claims 59-73 relate to diagnostic kits having FEN-1 proteins and oligonucleotides capable of forming specific cleavage structures).

7) The subject matter of new Claims 7-73 has never been presented or examined before the present reissue application.

8) All of the new claims recite a "double flap" cleavage structure (*i.e.*, a structure containing an oligonucleotide with a 3'-flap and an oligonucleotide with a 5'-flap).

9) The original text of the specification provides no description of "double-flap" structures of the new claims.

10) As prosecuted, the original application did not contain the essential matter necessary to support the new reissue claims.

11) The only potential support for the "double-flap" structure comes from the reference Harrington and Lieber (*J. Biol. Chem.*, 270:4503 [1995]) which is incorporated by reference, along with other references, in the '283 patent.

12) The Harrington and Lieber reference does not describe methods of detecting a target nucleic acid in a sample.

13) The Harrington and Lieber reference does not describe any kits, let alone diagnostic kits.

14) The Harrington and Lieber reference is only incorporated by reference into the '283 patent for describing specific aspects of basic research binding and cleavage studies.

15) The '283 patent provides a brief prophetic description of diagnostic methods and kits. These descriptions simply apply the alleged inventive FEN-1 endonucleases to known cleavage methods and uses.

16) The portion of the '283 patent describing diagnostic methods and kits does not refer to "double-flap" structures, and does not incorporate the Harrington and Lieber reference.

17) Neither the '283 patent, nor the Harrington and Lieber reference, contain many of the words and phrases now appearing in Claims 7-73.

18) The claims filed in the original application were directed to specific FEN-1 endonuclease proteins, nucleic acids encoding the specific FEN-1 endonuclease

proteins, and host cells containing specific FEN-1 endonuclease proteins or nucleic acids encoding specific FEN-1 endonucleases.

19) During the original prosecution, the Examiner issued a restriction requirement, separating the pending claims into two groups: 1) FEN-1 proteins and 2) nucleic acids encoding FEN-1 polypeptides and host cells containing FEN-1 proteins and nucleic acids.

20) In response to the restriction requirement, Applicants elected, without traverse, to pursue the FEN-1 encoding nucleic acid claims.

21) Applicants never filed a divisional application to pursue the non-elected protein claims.

22) The elected claims were directed to sequences comprising a sequence substantially similar to at least a portion of SEQ ID NO:1 or 3.

23) The Examiner issued an Office Action rejecting the elected claims as being non-enabled and being unpatentable in view of the prior art.

24) Applicants narrowed their claims to overcome the Examiner's rejections.

25) The narrowed claims, which issued in the '283 patent, were directed to particular sequences - SEQ ID NO:1 or 3 or active fragments of SEQ ID NO:1 or 3.

26) The new reissue claims encompass subject matter surrendered during the original prosecution of the patent.

27) The new reissue claims contain new matter.

28) The reissue declarations of the inventors state in part "[a]t the time the original patent issued, Applicants failed to recognize that the application as filed disclosed patentable inventions beyond those originally and ultimately claimed. The originally disclosed but unclaimed inventions are embodied in claims 7-73 of the Preliminary Amendment submitted concurrently with the reissue application Serial No. 09/586,744."

ARGUMENTS

I. This Application is Not Based on a Recognized "Error"

For a reissue to be proper, there must be "error" with respect to "the claims." 35 U.S.C. 251, yet in the present case, Applicants seek a reissue where the original six claims are maintained *unchanged*! Clearly, there was no error with respect to the issued claims. Instead, the new owners of the patent merely seek to "mine the patent" for additional inventions, created in hindsight, years after the original filing. This is not error for which the reissue remedy is appropriate.

In the present reissue application, Applicants have not identified an "error" that can properly form the basis for a reissue application. The declaration filed fails to specifically identify 'at least one error' in the specification or original claims (MPEP 1414). Where the declaration filed does attempt to identify an error, the error recited (failure to recognize an alleged invention) does not provide proper grounds for reissue of the patent (MPEP 1402). Instead, Applicants are seeking to claim in this reissue application an invention they intentionally chose not to prosecute, and that they abandoned upon restriction in the original application. The Federal Circuit has made it very clear that failing to present a set of claims in an original application where there has been a restriction requirement precludes an applicant from claiming "error" during reissue for failing to pursue these claims (*In re Weiler*, 790 F.2d 1576, Fed. Cir. 1986, *see also* MPEP 1402).

A. Applicants Have Not Pointed To 'At Least One Error' In The Original Patent

Under 37 C.F.R. 1.171 Applicants are required to submit a reissue declaration that complies with 37 C.F.R. 1.175. MPEP 1414 describes what the reissue declaration must

contain in order to comply with 37 C.F.R. 1.175. In particular, MPEP 1414 indicates that the reissue declaration must contain "[a] statement of **at least one error** which is relied upon to support the reissue application, *i.e.*, as the basis for the reissue" (*emphasis added*). MPEP 1414 further specifies that "[a] reissue applicant must acknowledge the existence of an error in the specification, drawings, or claims, which error causes the original patent to be defective" and "[in] identifying the error, it is sufficient that the reissue oath/declaration identify a single word, phrase, or expression in the specification or in an original claim ..." (*emphasis added, See,* MPEP 1414, section II, ¶5). Even with this minimal requirement - a single word, phrase, or expression - Applicants have failed to identify such an error in this reissue application.

The reissue declaration filed by the inventors in this reissue application merely states that:

> "**[a]t least one error** upon which reissue is based is described as follows: At the time the original patent issued, Applicants failed to recognize that the application as filed disclosed patentable inventions beyond those originally and ultimately claimed. The originally disclosed but unclaimed inventions are embodied in claims 7-73 of the Preliminary Amendment submitted concurrently with the reissue application Serial No. 09/586,744." (*emphasis added*).

Nowhere in this declaration do the Applicants point to an error in a single word, phrase, or expression in the specification or an original claim, as indicated by MPEP 1414. Instead, the "error" cited by the Applicants, is in the minds of the inventors (*i.e.* failing to recognize the alleged inventions), with no connection to any mistake in the specification or the original claims. As such, the reissue declarations signed by the inventors are defective, in that the alleged "error" does not qualify as an error under MPEP 1414[3].

Applicants may point to the phrase in the reissue declaration "disclosed but unclaimed invention are embodied in claims 7-73 of the Preliminary Amendment submitted concurrently with the reissue application", asserting that it provides sufficient error. However, pointing to **new** claims does not satisfy the requirement in MPEP 1414 that the declaration identify error in the specification, drawing, or **original claims**. Likewise, it would not be sufficient for the

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[3] The Examiner is directed to form paragraph 14.01.01 "No Statement of Specific Error", or alternatively form paragraph 14.01.02 "The Identified 'Error' Is Not Appropriate Error".

Applicants to point to the entire contents of the Preliminary Amendment, as the MPEP specifically states:

> "It is not sufficient for an oath/declaration to merely state 'this application is being filed to correct errors in the patent which may be noted from the changes made in the disclosure.' Rather, the oath/declaration must specifically identify an error". (*emphasis in original,* MPEP 1414, section II, ¶6).

Therefore, it is clear that the Applicants' reissue declarations are defective, and cannot be rectified by a general citation to the accompanying Preliminary Amendment.

B. Applicants' Alleged 'Error' Is Not A Proper Grounds for Filing

The proper grounds for filing a reissue application are provided in MPEP 1402. This section of the MPEP also provides examples of what does not qualify as error. The present reissue application fails to provide such proper grounds. Indeed, it is believed that the 'error' alleged in this declaration is specifically excluded, in keeping with the MPEP's guidance of what does not qualify as an error.

i. Not alleging error in SCOPE of the Claims

MPEP 1402 provides four bases for 'error' in filing a reissue application: "(A) the claims are too narrow or too broad; (B) the disclosure contains inaccuracies; (C) applicant failed to or incorrectly claimed foreign priority; and (D) applicant failed to make reference to or incorrectly made reference to prior copending applications" (*emphasis added*, MPEP 1402). The declaration filed by the Applicants does not allege any of these bases of 'error'. Instead, the inventors admit to "failing to recognize patentable inventions". However, MPEP 1402 is clearly discussing the scope of the claims as an error, not the failure to recognize totally separate inventions.

The MPEP (1402) and the statute (35 USC 251) refer to an error in "**the** claims". In particular, MPEP 1402 states "[a]n attorney's failure to appreciate the full scope of the invention was held to be an error correctable through reissue" (*emphasis added*, MPEP 1402, *citing In re Wilder*, 736 F.2d 1516, Fed. Cir. 1984). Clearly, MPEP 1402 only recognizes an

error in the scope of the original claims, not the wholesale substitution of separate and distinct claims[4].

The Applicants may seek support for this application by citing cases where the omission of claims in a different statutory category was allowed to serve as a valid error for seeking reissuance, as in *Scripps Clinic & Research Foundation v. Genentech*, 927 F.2d 1565 (Fed. Cir., 1991). In *Scripps*, the court allowed the omission of product claims to serve as a valid basis for seeking reissuance. The original claims in *Scripps* were process and product-by-process claims to human Factor VIII:C. The attorney prosecuting the original claims held the initial view that product claims were unavailable (*i.e.* ATTORNEY ERROR). The court found that this type of error of law was available as a proper error for reissue in allowing the failure to originally present the product claims to serve as error. However, that case involved claim SCOPE and ATTORNEY ERROR (*i.e.* the basis for error provided in MPEP 1402).

The product claims added in *Scripps* were not to some separate and distinct invention, but instead, were to human VIII:C (the product of the previously claimed process and product-by-process claims). The court in *Scripps* recognized that this was a SCOPE issue based on ATTORNEY ERROR, explicitly stating "the whole purpose of the statute, so far as claims are concerned, is to permit limitations to be added to claims that are too broad or to be taken from claims that are too narrow", and stating that "[a]n attorney's failure to appreciate the full scope of the invention was held to be an error correctable through reissue" (*emphasis added*). Therefore, it is clear that *Scripps* is consistent with the grounds for finding error in MPEP 1402 (Claim Scope and Attorney Error), and does not authorize Applicants' attempt to premise 'error' on the INVENTORS' failure to recognize a totally divergent invention.[5] In fact, it would be **unprecedented** to allow Applicants' failure to recognize the invention or the presentation of separate and distinct claims to serve as 'error' for this reissue application.

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[4] The newly added reissue claims (7-73) are clearly separate and distinct from any claims previously presented by the Applicants. During the prosecution of the original patent the Examiner issued a restriction requirement. In this restriction requirement, the FEN-1 polypeptide claims were classified in class 435, subclass **199**, and the polynucleotide claims were classified in class 435, subclass **252.3**. The newly added claims would be classified, for example in class 435, subclass **6** (note the word "target" or "bridge polynucleotide (*i.e.* target) in all of the newly presented claims). Thus, newly presented claims 7-73 are clearly separate and distinct.

[5] The fact that this case does not involve any alleged Attorney Error makes this reissue highly unusual, and not supported by reference to the MPEP.

It is clear that the Applicants' alleged error of failing to recognize alleged inventions, and present these claims in the original application is not an acceptable error under the MPEP or Federal Circuit precedent. The reissue declarations are defective for failing to provide a proper ground for filing this reissue application. Any attempt by Applicants to correct the declarations must involve identification of an error in the scope of the original claims, and necessarily requires deletion of all new claims directed to different inventions (it is further noted that any broadening of the original claims may run afoul of the recapture doctrine - *see* Section III).

ii. Failure to File A Divisional Was Not 'Error'

MPEP 1402 not only provides direction as to acceptable error, but specifically indicates that an applicant's failure to file a divisional application is not considered to be an acceptable error forming grounds for filing a reissue application. The Federal Circuit has explained that this 'lack of error' also applies to claim sets not originally presented in cases where a restriction requirement was made during original prosecution (*In re Weiler*, 790 F.2d 1576, Fed. Cir. 1986).

During the prosecution of the original patent in this case, the Examiner restricted the claims into two groups. The Claims in Group I (Claims 1-5) were drawn to FEN-1 polypeptides and the Claims in Group II (Claims 6-11) were drawn to polynucleotides encoding FEN-1 polypeptides and host cells containing FEN-1 polypeptides. The Applicants elected Group II, Claims 6-11 (FEN-1 polynucleotides) without traverse. Subsequently, the Claims in Group 1 (Claims 1-5) were cancelled and the '283 patent was issued. However, the applicants failed to file a divisional application pursuing the subject matter of Claims 1-5 (*i.e.* FEN-1 polypeptides). Even if Applicants argue that they were in possession of the alleged invention at the time the original application was filed (which they say in their declaration they were not), Applicants failed to present these claims in the original application or in any divisional or continuation application.

The Federal Circuit has squarely addressed this situation, and flatly rejected an Applicant's attempt to characterize this as acceptable 'error' (*In re Weiler*, 790 F.2d 1576, Fed. Cir., 1986, which is attached to this protest, at Appendix A, for the Examiner's convenience). The court in *In re Weiler*, affirming the Appeal Board's and Examiner's

rejections, refused to recognize failure to file a divisional application for either non-elected inventions, or previously unclaimed inventions as an "error" that could be remedied by reissue. In particular, the court states:

> "By acquiescing in the examiner's restriction requirement, and failing to file divisional applications on the subject matter of non-elected claims, Weiler foreclosed (because that was not error) his right to claim that subject matter. If it were not error to forego divisional applications on subject matter to which claims had been made in the original application, it cannot on the present record have been error to forego divisional applications on subject matter to which claims had never been made (*emphasis added, id.* at 1582).

Likewise, in the present reissue application, a restriction requirement was issued by the Examiner during prosecution of the original patent, and Applicants failed to file a divisional application on the non-elected claims to FEN-1 polypeptides, or to originally present or otherwise pursue the newly added reissue claims. According to *In re Weiler*, it cannot be viewed as "error" that Applicants elected "to forego divisional applications on subject matter to which claims had never been made" (*i.e.* present claims 7-73).

The particular facts of *In re Weiler* are discussed in detail below for the Examiner's convenience, as they relate to the present case. In *In re Weiler*, the original claims were restricted into 3 groups (claims 1-7 to assay methods, claims 8 and 11 to organic compounds, and claims 9 and 10 to protein compounds). Applicants elected claims 1-7 and did not file any divisional applications. When additional claims were sought in reissue, the court upheld the Examiner's decision that reissue claims 14-18 were not allowed to be pursued, as they corresponded to original claims 9 and 10, for which no divisional application was ever filed. More importantly, reissue claims 13 and 19 were not allowed to form the basis of 'error' because they HAD NEVER BEEN presented and were found to be distinct from the 3 original groups that were restricted. As such, the applicants in *In re Weiler* were not allowed to present these claims on reissue, even though section 112 support could be found in the original application. The court explained:

> "The subject matter of Claims 13 and 19 are clearly independent of and distinct from each other, from that of elected claims 1-7, from that of non-elected organic compounds claims 8 and 11, and from that of non-elected protein compound claims 9 and 10. Weiler would thus have had no right to insert and present claims 13 and 19 in the original application after the Examiner's requirement for restriction" (*emphasis added*, id. at 1581); and

"Here too, the question redounds to one of error, for when an applicant makes some disclosure, as Weiler did, of as many as five distinct inventions, claims one, and ignores the rest, it is difficult to find error in the failure to claim those ignored on the sole basis that they were disclosed. To so hold would render meaningless the statutory requirement that an applicant point out out and distinctly claim subject matter he regards as his invention". 35 U.S.C. § 112, 2d¶ (*emphasis added, id.* at 1581).

The facts in *In re Weiler*, as stated above, clearly present the same situation as the present application. Again, in the present application, Applicants: 1) never presented the subject matter of reissue claims 7-73[6]; 2) the original application was subject to a restriction requirement; and 3) Applicants failed to pursue a divisional application on the non-elected set of claims. Therefore, Federal Circuit precedent makes it clear that the Applicants do NOT have a valid 'error' for this reissue application, making this application void.

II. Reissue Claims *do not* meet the "Same General Invention" Requirement

The MPEP requires that the reissue claims must be for the *same* invention. MPEP 1412.01. The Federal Circuit has indicated that the proper test to determine whether the reissue claims are for the same invention is to ascertain whether "one skilled in the art, reading the specification, would identify the subject matter of the new claims as invented and disclosed by the patentees" (MPEP 1412.01, *citing In re Amos*, 953 F.2d 613, 618 (Fed. Cir., 1991). In the present case, Applicants admit that one skilled in the art would not identify the subject matter of the new claims in either the original specification or amended specification. Furthermore, Applicants have imported essential matter into the application - *matter which was merely referenced in the original application.* Thus, there is no basis within the original specification by which one skilled in the art would know or appreciate Applicants had allegedly invented and disclosed the subject matter of the new claims.[7]

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[6] To the extent any of the originally filed claims relate to new reissue claims 7-73, it is the non-elected claims. Therefore, to allow Applicants to pursue new claims 7-73 would result in improper recapture of subject matter they intentionally abandoned by choosing not to file a Divisional application -- *see* Section III).

[7] Indeed, even if this matter is "incorporated by reference" in the original specification, the importation of essential material into the specification in a reissue would appear to establish an irrebuttable showing of lack of intent regarding the newly claimed invention.

A. Applicants (As Ones Skilled In The Art) Failed To Recognize The Alleged Inventions

All three inventors state in their reissue declarations that "[a]t the time the original patent issued, Applicants failed to recognize that the application as filed disclosed patentable inventions beyond those originally and ultimately claimed" (*emphasis added*). This is fatal to Applicants request for reissue. Applicants are skilled in the art. If they failed to recognize the subject matter later claimed, certainly others skilled in the art, who are not as close to the particular subject matter, would not recognize the subject matter later claimed. As such, Applicants have admitted that they fail the 'same invention' test as articulated in *In re Amos*.

Applicants may argue that they need only meet the section 112 requirements to satisfy the 'same invention' requirement. However, their own admission concerning their failure to appreciate the newly claimed invention dooms them under a section 112 analysis. For example, to satisfy the written description requirement "an applicant must convey with reasonable clarity to those skilled in the art that, *as of the filing date sought*, he or she was in possession of the invention, in that context, of whatever is now claimed" (MPEP 2163.02). Applicants have admitted that they were not in possession of the alleged invention at the time the application was filed, thus defeating any section 112 arguments Applicants may present. At best, Applicants would receive the filing date of the present reissue application as their filing date.

B. The Named Inventors Could Not Have Conceived Of The New Invention Until After February 23, 1999

The named inventors signed a declaration in the original case attesting to the fact that they understood the contents of the application. They now swear in their reissue declarations that "at the time the original patent issued" that they failed to recognize the alleged patentable subject matter now sought to be claimed. One can only conclude that the named inventors did not CONCEIVE[8] of the new claims - if they *ever* did - until after the original patent

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[8] As noted in *Burroughs Wellcome Co. v. Barr Laboratories*, 40 F.3d 1223, 1231 (Fed. Cir., 1994), "[f]or conception, we look not to whether one skilled in the art could have thought of the invention, but whether the alleged inventors actually had in their minds the required definite and permanent idea" (*emphasis added*).

issued (*i.e.* February 23, 1999)[9]. Since the conception dates for the alleged inventions are not the same, this is further evidence that the reissue request is not for the same invention.

C. The Original Patent Does Not Disclose Subject Matter of New Claims

According to *In re Amos*, one skilled in the art, reading the specification must be able to identify the subject matter of the new claims as invented and DISCLOSED by the patentees. The present reissue application fails this test, as the subject matter of the new claims is not disclosed in the original specification.

In this reissue application, Applicants have amended the specification by inserting selected portions of a paper by Harrington and Lieber (Harrington and Lieber, *J. Biol. Chem.* 270:4503 [1995]). Applicants may argue that the pages of text from the Harrington and Lieber paper inserted into the original patent should lawfully be considered as part of the "original patent" because it was incorporated by reference in the original specification. Applicants must take this position because all of the newly added claims concern a "double flap" nucleic acid structure that was NOT disclosed in the original specification or figure. The original specification must be supplemented in an attempt to satisfy section 112 requirements for the newly added claims. However, even setting aside momentarily the question of the propriety of incorporation of new material, the additions to the specification do not make the newly claimed invention part of the "original patent".

The "original patent" requirement in MPEP 1412.01 is for the purposes of determining if the same invention requirement has been met, not whether the Applicants have met the section 112 requirements in the disclosure.[10] Applicants will likely focus arguments on the

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[9] The likely explanation is that the new owners recognized alleged patentable subject matter - not the named inventors.

[10] The Federal Circuit has recognized, simply meeting 112 requirements in reissue claims does not alone establish intent to claim (*See, In re Weiler*, 790 F.2d 1576, 1581-82, Fed. Cir., 1986, stating "It is true that absence of compliance with § 112 will foreclose a finding of "intent" and preclude grant of the reissue, but, as indicated above, the absence dooms the application in any event. The converse is not true. Compliance with § 112 does not alone establish "intent to claim" and does not alone establish error in a failure to claim". Applicants may cite *In re Amos*, in support of the contention that meeting 112 requirements satisfies the "intent to claim" requirement, however, *In re Amos* specifically states "the issue of whether the tests, for written description and enablement under § 112 ¶ 1 and for "same invention" under § 251, are in every case exactly co-extensive, neither briefed nor argued in this case, is not properly before us on the instant facts ...".

legality of amending the specification to include material previously incorporated by reference (*e.g.*, they may cite MPEP 608.01(p)(A)(2) in support of their position).[11] In other words, Applicants will likely argue that the new material added to the specification is not technically new matter. However, simply amending the specification **does not** address the issue of whether one skilled in the art would recognize the invention was disclosed by the patentees in the original patent.

The original patent as filed clearly does not disclose the "double flap" structures that have become the **centerpiece** for all the newly added reissue claims. Indeed, the limited disclosure relating to diagnostic methods and compositions makes no note of such structures or the reference that Applicants are now attempting to incorporate into the specification to support claims to diagnostic methods and compositions. The description in the original patent text, are 5' flap structures (as shown in figure 6) and not 'double flap' structures, as diagramed in new figures 11 and 12. The prophetic section of diagnostic methods are prior art methods employing the mammalian FEN-1 enzyme allegedly discovered by the patentees (*See, e.g.*, single flap prior art methods - Gelfand *et al.*, U.S. Pat. 5,210,015 (*See, e.g.* Example 5), included with this protest at Appendix B). The application as filed did not contain any description of the "double flap" structures now presented in all of the newly added reissue claims; the only potential description of these structures is found in the Harrington and Lieber reference. In other words, the specification only "discloses" double flap structures if the material in the Harrington and Lieber reference is physically added.[12]

The Supreme Court has squarely addressed this situation where an Applicant is attempting to amend the specification during reissue with material that was ancillary to the original specification. In particular, in *Parker & Whipple Co. v. Yale Clock Co.*, 123 U.S. 87, 8 S.Ct. 38, S.Ct. 1887, the Supreme Court indicated that the invention of a reissue patent must be the invention described in the specification of the Original Patent, and a reissue attempting to claim (as part of the invention) embodiments shown in a model accompanying

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[11] Applicants may attempt to claim that the "error" in their original patent was the failure to actually incorporate the text of the Harrington and Lieber paper into the patent. However, far from demonstrating error, this simply highlights the fact that Applicants did not appreciate the alleged existence of the inventions now claimed.

[12] Without bodily incorporating the text of the Harrington and Lieber reference into the specification, Applicants could not have pursued the new reissue claims in the original case.

the original application (that were not claimed in the original application as forming part of the original invention) is void. Likewise, in the present application, the paper incorporated by reference (like the model in *Parker*) was ancillary to text in the specification, and cannot now (in reissue) be added to the specification to support the pursuit of newly added claims unsupported by the original specification.

The Supreme Court in *Parker & Whipple Co.* recites the dangers in allowing an applicant to add additional material regarding a separate invention to a reissue application and then pursue claims based on this material:

> "The danger to be provided against was the temptation to amend a patent so as to cover improvements which might have come into use, or might have been invented by others, **after its issue**. The legislature was willing to concede to the patentee the right to amend his specification so as fully to describe and claim the very invention attempted to be secured by the original patent, and which was not fully secured thereby, in consequence of inadvertence, accident, or mistake; but was not willing to give him the right to **patch up his patent** by the addition of other inventions, which, though they might be his, had not been applied for by him, or, if applied for, had been abandoned or waived. For such inventions he is required to make a new application, subject to such rights as the public and other inventors may have acquired in the mean time." *(emphasis added, Parker & Whipple*, 123 U.S. 45-46).

The same danger is present in the present application. To allow the present Applicants to patch up their application with material only ancillary to the original specification,[13] and use this as the basis of newly presented claims, risks rewarding Applicants for hindsight inventions, controverts Supreme Court precedent and is not fair to the public. Drafting reissue claims on the basis of incorporated material (never the intent of the legislature) unfairly deprives the public of notice of proper scope of the patent, while simultaneously permits Applicants to claim, based on hindsight, "improvements which might have come into use, or might have been invented by others." This is not the purpose of the reissue procedure.

D. Separate and Distinct Claims Cannot Be "The Same Invention"

As pointed out above, the new claims being pursued in this reissue application diverge dramatically from the claims originally patented and presented by the inventors as their

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[13] Material that those skilled in the art would not recognize as part of the invention (indeed, material the inventors themselves did not recognize).

original invention (*i.e.* the original claims are for polynucleotides encoding specific polypeptide sequences, and the newly added reissue claims relate to diagnostic methods and compositions). Over the past 125 years, courts have struggled with the issue of whether it is permissible to present claims in a reissue application that, even though possibly related to the originally patented claims, are in a different statutory category (*e.g.* presenting method claims in a reissue application that directly correspond to the composition claims already patented). The courts have struggled with whether or not the newly added reissue claims are for the same invention[14] as the originally patented claims, and/or whether failure to present these claims originally provided an acceptable basis of an alleged "error"[15] (*see* part I above).

However, in the present case, Applicants have **gone far beyond** attempting to present claims in a different statutory category than the polynucleotide sequences originally patented, and instead are attempting to present a wholly separate invention unrelated to the polynucleotide sequences patented in the original patent. In other words, Applicants are not merely attempting to pursue methods of making the previously patented polynucleotide sequences, which would be questionable under current case law, but instead are shamelessly attempting to pursue entirely different inventions (*e.g.* methods and compositions containing a "double flap" structure). This is not proper and the law has no uncertainty in such cases -- such claims are forbidden according to controlling Supreme Court precedent.

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[14] - *Rohm & Haas Co. v. Roberts Chemicals*, 245 F.2d 693 (4th Cir., 1957) - originally patented claims were all composition claims for salts of bisdithiocarbamic acid, and reissue claims granted were all for process claims employing the salts of bisdithiocarbamic acid to control fungus growth on living plants. The court did not rule on whether failure to pursue related method claims was a proper error for reissue because it found an alternative basis for the error.

- *In re Rowand*, 526 F.2d 558 (CCPA, 1975) - originally patented claims were composition claims for a teflon tube, and the reissue claims methods of making the teflon tube. The court rejected the reissue claims (even though they were for the same general invention as the original claims) agreeing with the board that "nothing in the original patent evidencing that appellants intended to claim a method of making tubing or that appellants considered the method now claimed to be their invention." *Id.* at 560. This case also noted that title of the invention and other portions of the specification were focused on compositions, not methods.

[15] - *Scripps Clinic & Research Foundation v. Genentech*, 927 F.2d 1565 (Fed. Cir., 1991) - originally patented claim were to methods of preparing and purifying factor VIII:C, and the reissue claims were all to purified factor VIII:C compositions. In this case the court held that the omission of product claims was a valid basis for seeking reissue. However, the product claims that were allowed to be added by reissue, and the original method claims, all regarded factor VIII:C (the court did not say that divergent claims may be a valid reason to seek reissue).

In *Powder Co. v. Powder* Co., 98 U.S. 126, 25 L.Ed. 77, (Sup.Ct, 1878), the Supreme Court firmly rejected an attempt by an Applicant to pursue such distinct inventions in a reissue application and explained that the reissue claims must be directly related to the original claims. The originally patented claims in the *Powder Co.* case were for a process for exploding nitroglycerine, whereas the reissue claims were for mixtures of nitroglycerine with gunpowder, guncotton, and rocket powder. The court concluded that "[i]nasmuch as the reissued patents in question ... are for compounds of nitroglycerine with various other substances, it is impossible not to say that they are for an entirely different invention from that secured, or attempted to be secured, by the original patent." *Id.* at 136. The following statement from *Powder Co.* is instructive:

> "The processes which the patentee described as his invention in the original patent, No. 50,617, had no connection with the compounds or mixtures which are patented in the reissued patents. They were not processes for making those compounds, and in describing them the compounds were not mentioned. The invention of the one did not involve the invention of the other. The two inventions might have been made by different persons, and at different times. We think, therefore, that the conclusion is irresistible, that the two reissued patents ... are for a different invention from that described or suggested in the original patent." *(emphasis added, Id.* at 137).

Based on this reasoning, the Court in *Powder Co.*, held "[s]ince, therefore, the reissues in question are not for the same invention for which the original patent was granted, it follows that they are void ...". *Id.* at 139.

The *Powder* case provides bright line rules for determining whether other claim types may be added in reissue. The *Powder* case permits adding claims which are very closely inter-related, such as the addition of method claims involving the production of the originally claimed compositions.[16] However, the addition of method claims which teach the diverse *uses* of the claimed compositions are NOT permitted.[17]

Thus, in the present application, the newly presented reissue claims are clearly not for the same invention for which the original patent was granted. In particular, the original claims are to particular polynucleotide sequences encoding FEN-1 polypeptides, and host

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[16] The *Scripps* cases (where composition claims were added in reissue to original process and product by process claims) is in complete agreement with *Powder*.

[17] These distinctions are not arbitrary, instead they are consistent with modern restriction practice. Moreover, the Supreme Court in *Powder* has struck a balance between fairness to the applicant and fairness to the public (consistent with the equitable spirit of the reissue statute).

cells, and the newly added claims are directed to diagnostic methods and unrelated compositions involving a "double flap" nucleic acid structure. Therefore, these reissue claims are void.[18]

As such, based on Supreme Court precedent, among other grounds, the Examiner should require Applicants to cancel newly presented reissue claims (*i.e.* claims 7-73) from this reissue application. To allow Applicants to pursue such divergent claims in this reissue would be **unprecedented**. To allow the reissue to proceed with the newly added reissue claims would be permitting misuse of the reissue statute, and would be contrary to law.

III. Applicants are Improperly Attempting to Recapture Canceled Subject Matter

As discussed above, the original application was directed to mouse and human FEN-1 endonucleases and the Applicants originally chose to pursue claims to nucleic acids encoding these FEN-1 endonucleases and host cells containing the FEN-1 endonucleases encoded by these nucleic acids. During the prosecution of the claims in the original patent, the Applicants chose to narrow their claims in response to rejections by the Examiner. As discussed in detail below, Applicants are now trying to recapture subject matter that was previously surrendered in the prosecution of the original case. A reissue will not be granted to "recapture" claimed subject matter that was surrendered in an application to obtain the original patent (MPEP 1412.02; *In re Clement*, 131 F.3d 1464, 45 USPQ2d 1161 (Fed. Cir. 1997)).

The MPEP provides guidance for determining if improper recapture has taken place (MPEP 1412.02). The first step is to review each claim for the presence of broadening, as compared with the scope of the claims of the patent to be reissued. A reissue claim is broadened where some limitation of the patent claims is no longer required in the reissue claim. The MPEP directs one to MPEP 1412.03 for guidance[19] as to the nature of what constitutes "broadening." Section 1412.03 explains that a claim is "broadened" if the claim of

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[18] It should be noted that the present situation does involve inventions made "at different times" (*See, Powder Co, supra*). On this basis alone, the new claims do not satisfy the "same invention" requirement.

[19] MPEP 1412.02 contains the passage "See MPEP Section 1412.03 for guidance as to the nature of a 'broadening claim'."

the reissue application enlarges the scope of the claims of the patent in at least one aspect, even though it may be narrower in other respects. To help in this analysis, the MPEP explains that if any amended or newly added claim in the reissue contains within its scope any conceivable product or process which would not have infringed the original patent, then that reissue claim would be broader than the patent claims.[20] Although one is generally able to broaden claims during a broadening reissue (*i.e.*, capture infringers who otherwise would not have infringed the originally issued claims), there is no tolerance for broadening claims by resurrecting subject matter that was surrendered during the original prosecution.

The New Claims Are Broader

In the present case, each of the new claims is broader than the originally issued claims with respect to the FEN-1 endonucleases. Specifically, Claim 1 of the originally issued patent, the broadest claim of the originally issued patent, recited:

> 1. An isolated polynucleotide encoding a Fen-1 polypeptide as shown in SEQ ID NO 1 or SEQ ID NO 3, or a fragment of said polypeptide having flap endonucleolytic cleavage activity.

Thus, with respect to the FEN-1 element, the originally patented claims required the FEN-1 to be that of SEQ ID NO 1, SEQ ID NO 3, or a functional fragment of SEQ ID NO 1 or SEQ ID NO 3. The new claims are much broader with respect to this element. New Claim 7 is extremely broad as it specifies cleavage without being limited to any particular cleavage means. Not only does Claim 7 not require the cleavage means to be SEQ ID NO 1, SEQ ID NO 3, or a functional fragment of SEQ ID NO 1 or SEQ ID NO 3, it does not even require

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[20] Even though a claim may be narrower in some aspects, if it broadens any element, it is conceivable that products or processes would infringe the new claim. For example, if the original claims were to a "blue box" and the new claim were to a "box with handles," the new claim is broader in some respects (isn't limited to a color) while narrower in others (the original claim doesn't require handles like the new claim). However, the new claim is considered broadened for the purpose of reissue because a manufacturer of a red box with handles would infringe the new claim, but would not infringe the original claim (*i.e.*, the broadening of the color element sweeps in potential infringers who otherwise wouldn't have infringed without the broadening).

that the cleaving occur by a FEN-1 endonuclease. The same holds true for new claims 8, 9, and 14-20.

Claim 10 states that the cleavage occurs with a yeast or mammalian FEN-1 polypeptide. Again, this is much broader then the specific SEQ ID NOs recited in the originally patented claims. Claim 11 states that the FEN-1 polypeptide of Claim 10 is a human FEN-1 polypeptide comprising the amino acid sequence shown in SEQ ID NO:1 or a fragment thereof. This is also broader than the originally patented claims which state that the polypeptide is (*i.e.*, consists of) SEQ ID NO:1 or a fragment thereof. In other words, Claim 11, with the open "comprising" language encompasses FEN-1 polypeptides with sequence in addition to SEQ ID NO:1. Claim 12 is similar to Claim 11, but recites the mouse FEN-1 SEQ ID NO:3. This claim also has the "comprising" language and is broader than the originally issued claims. Claim 13 is directed to specific yeast FEN-1 endonucleases. This claim is broader than the originally issued claims, which do not encompass yeast FEN-1 endonucleases.

New Claims 21-50 are also broader than the originally issued claims using the same analysis as above. For example, new Claims 21 and 36 are directed to methods using "a FEN-1 polypeptide." This is broader than the originally issued claims which were limited to specific SEQ ID NOs claimed in the originally issued claims. Certain dependent claims recite polypeptides comprising SEQ ID NOs 1 or 3. As discussed above, these claims are also broader than the originally issued claims with respect to the FEN-1 element.

New Claims 51-58 are directed to hybridization complexes comprising several specific polynucleotides. These claims are so broad as to not even recite a FEN-1 endonuclease. None of the claims limit the scope of a FEN-1 endonuclease provided in conjunction with the polynucleotides and are therefore broader with respect to this element than the originally issued claims.[21]

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[21] Any attempt to argue that the lack of a recitation of FEN-1 endonucleases in this set of claims precludes a "breadth" comparison would be disingenuous. At best, such an argument is an admission that the claims are completely separate and distinct from the originally pursued claims--rendering the claims improper for reissue as discussed in Section II of this protest (*i.e.*, since these claims don't share an element in common with the original claims, they are, without question, a different invention). Thus, the absence of the FEN-1 element in these claims only underscores that attempt to obtain claims much broader than originally filed (and broader than the specification permits). Furthermore, as detailed in Section IV of this protest, by failing to recite a FEN-1 endonuclease in the claims, Applicants have inappropriately introduced new matter into the specification.

New Claims 59-73 are directed to kits containing a FEN-1 polypeptide, among other components, and are broader than the originally issued claims. For example, new Claim 59 is directed to kits comprising "a FEN-1 polypeptide." This is broader than the specific SEQ ID NOs claimed in the originally issued claims. Certain dependent claims recite polypeptides comprising SEQ ID NOs 1 or 3. As discussed above, these claims are also broader than the originally issued claims with respect to the FEN-1 element.

Because each of the new claims is broader in at least one aspect than the original claims, the first prong for establishing improper recapture has been met. The MPEP next instructs that where a claim in a reissue application is in fact broader, the examiner must next determine whether the broader aspects of that reissue claim relate to subject matter that applicant previously surrendered during the prosecution of the original application (which became the patent for which reissue is sought). If the limitation now being broadened (*i.e.*, limitation to certain FEN-1 endonucleases) in the present reissue was originally present, argued, or stated in the original application for the purpose of making the claims allowable over a rejection or objection made in the original application, then the limitation does relate to subject matter previously surrendered by Applicants, and impermissible recapture does exist. This is clearly the case in the present reissue application.

The Issued Claims Were Narrowed in Prosecution to Overcome the Examiner's Rejections

The claims as filed in the original application were broader than the issued claims in the original patent (*i.e.*, the claims were narrowed during prosecution of the original patent). Specifically, Claim 6 as filed evolved into issued Claim 1. As filed, this claim was drawn to polynucleotides encoding a polypeptide comprising at least 25 consecutive amino acids substantially identical to SEQ ID NO:1 or SEQ ID NO:3. This claim is broader than the issued claim in several respects: it is open ended (*i.e.*, using "comprising"), allowing for sequences other than SEQ ID NO:1 and 3; it only requires that the sequence be substantially identical to SEQ ID NO:1 or 3, whereas the issued claims require absolute identity; and the filed claims have as few as 25 amino acids of SEQ ID NO:1 or 3, whereas the issued claims require at least a functional fragment thereof. Likewise, Claim 11 as filed evolved into issued Claim 5. As filed, the claim was drawn to any mammalian FEN-1 polypeptide in a non-

mammalian host cell. This issued claim is limited to SEQ ID NO:1, SEQ ID NO:3, and functional fragments thereof.

The Applicants narrowed the claims in the face of a rejection from the Examiner. For example, the Examiner rejected Claims 6-11 as not being enabled, "as the disclosure is enabling only for claims limited to polynucleotides encoding mouse/human flap endonuclease (FEN-1) of about 380 amino acids" (first office action, pages 2-3). The Examiner further specifically rejected open-ended language claiming additional sequences beyond SEQ ID NOs:1 and 3. The applicants amended their claims in response to these rejections. As amended, Claim 6 (issued Claim 1) removed the open-ended "comprising" language and Claim 11 (issued Claim 5) was limited to the same scope as Claim 6 (issued Claim 1) (*i.e.*, as opposed to the broader "mammalian FEN-1" language as filed).[22] Following a phone interview with the Examiner, the claims were further narrowed to their present state (*e.g.* removing the word "substantially"). Because the limitation now being broadened (*i.e.*, the FEN-1 endonuclease limitation) in the present reissue was narrowed in the original application specifically to make the claims allowable over a rejection made in the original application, the limitation relates to subject matter previously surrendered by Applicant. Impermissible recapture therefore exists for newly added reissue Claims 7-73.

Indeed, even the narrowest of the new reissue claims (*e.g.*, new Claim 11) recite sequences comprising SEQ ID NO:1 or 3. This is the exact subject matter that the Examiner rejected in the original prosecution and that the applicants narrowed to avoid the rejection. With respect to the FEN-1 aspect of the claims, all of the new reissue claims are as broad or broader than subject matter surrendered in the original prosection in response to PTO rejections. This is improper recapture and the Examiner should require the cancellation of these claims.

Applicants may argue that their amendments were not made to overcome the Examiner's rejections and objections, but instead were made for "other" reasons. This

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[22] Applicants may argue that Claim 11 was amended for the purpose of responding to an objection related to the dependency of the claims (the Examiner objected to several claims that were dependent on claims that had been canceled by the Applicant in response to a restriction requirement). This is disingenuous because Claim 11 was never dependent on another claim. Nonetheless, Claim 11 was limited to a scope narrower than any cancelled claim, showing that the narrowing was not to correct dependency but was for other reasons (*i.e.*, to avoid the Examiner's substantive rejections).

argument fails. The written record of the prosecution history clearly indicates that the amendments were made because of the rejections and objections. An office action was submitted with a number of rejections and objections. The Applicants narrowed the scope of their claims specifically in view of the rejections stating that "The Examiner has alleged that the disclosure is enabling only for claims limited to 'polynucleotide encoding mouse/human flap endonuclease (Fen-1) of about 380 amino acids.' . . . Applicants have amended claim 6 . . . Applicants believe that this amendment overcome (sic) the rejection and request that this rejection be withdrawn" (pages 2-3 of the amendment mailed on April 28, 1998).

Even if the Applicants had been silent on their reasons for narrowing the claims, they could not recapture the broader subject matter in reissue. The MPEP provides an example of how such a rejection is applied:

> "The original application claims recite limitations A+B+C, and the Office action rejection combines two references to show A+B+C. In the amendment replying to the Office action, applicant adds limitation D to A+B+C,[23] but makes no argument as to that addition. The examiner then allows the claims. Even though there is no argument as to the addition of the limitation D, it must be presumed that the D limitation was added to obviate the rejection. The subsequent deletion of (omission of) limitation D in the reissue claims would be presumed to be a broadening in an aspect of the reissue claims related to surrendered subject matter" (*emphasis added*).

Applicants are attempting to use this reissue proceeding to obtain claims that encompass all cleavage means and/or all FEN-1 endonucleases. This amounts to recapture of canceled subject matter and is forbidden. In the unlikely event such claims are granted, at most, Applicants claims must each be limited with regard to the FEN-1 endonuclease element to the scope of the originally issued patent (*i.e.*, limited to FEN-1 endonucleases represented by SEQ ID NO:1, SEQ ID NO:3, or functional fragments thereof).

While the Applicants generically stated that they "reserved the right to pursue any canceled subject matter in a continuation, divisional, or other related application" (page 2 of the amendment mailed on April 28, 1998), they chose not to file such applications. As discussed in Section I, reissue is improper where the "error" is a failure to file a continuation, divisional, or other related case. Applicants chose to limit the claims and chose not to obtain broader claims in a related application. Recapture prevents them from attempting to

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[23] In the present case this is the addition of the limitation that the sequence be limited to the specific SEQ ID NOs:1 or 3.

improperly recover the surrendered subject matter in a reissue case where the failure to originally obtain the claims was a matter of choice, not error.

Likewise, Applicants chose not to file divisional applications to recover subject matter lost in a restriction requirement. Reissue does not allow an Applicant to recover subject matter lost by failure to file a divisional application (*See* Section II). Therefore, Applicants are now limited in their ability to recapture claims involving FEN-1 polypeptides (*i.e.*, the subject matter that they abandoned by failure to file a divisional application). To the extent that any new "types" of claims would be allowable in this reissue application, they must relate to the subject matter that was elected by the applicants: nucleic acids encoding FEN-1 endonucleases or host cells containing FEN-1 endonucleases encoded by such nucleic acids. The new diagnostic method and kit claims violate this rule, because they recapture FEN-1 polypeptide subject matter that was abandoned by the failure to file a divisional application and do not relate in any way to the elected subject matter. Applicants may argue that the diagnostic method and kit claims are not purely "FEN-1 polypeptide" claims as abandoned in the original prosecution, but instead are methods and compositions that "involve" a FEN-1 polypeptide. This argument too must fail. The method and kit claims now pursued clearly related to uses of the non-elected "FEN-1 polypeptides," not uses of the elected "nucleic acids encoding FEN-1 polypeptides." For example, the kit claims could be drafted as dependent claims from the abandoned, non-elected polypeptide claims (*e.g.*, The FEN-1 endonuclease of Claim X, further comprising kit component 2, kit component 3, etc.) but could not be drafted from the elected nucleic acid claims. If permitted to obtain the pending method and kits claims, Applicants would be allowed to improperly recapture FEN-1 polypeptides. This is improper because Applicants chose to surrender the rights to FEN-1 polypeptides by failing to file a divisional application.

IV. Applicants have Improperly Added New Matter to the Reissue Application

New matter (*i.e.*, matter not present in the original patent sought to be reissued) is excluded from a reissue application in accordance with 35 U.S.C. 251 (MPEP 1411.02). The claims in the reissue application must be for subject matter which the applicant had the right to claim in the original patent. Matter not in the original specification, claims, or drawings is

usually new matter (MPEP 608.04[a]). In the present case, Applicants have improperly added new matter to the reissue application.

As discussed in the sections above, new claims 7-73 are directed to kits, hybridization complexes, and methods involving "double-flap" structures. The original specification provides no support for the "double-flap" structure. The only potential support comes from certain figures and text incorporated by reference from the Harrington and Lieber reference (*J. Biol. Chem.*, 270:1-6 [1995]). Because essential matter cannot be incorporated by reference from a publication, Applicants are now attempting to incorporate the selected text and figures (*i.e.*, Figure 5, now Figure 17) from the Harrington and Lieber reference into their reissue specification to support their new claims, while omitting other portions of the same Harrington and Lieber paper.[24] However, whether Applicants are permitted to add the Harrington and Lieber text or not, the specification does not support the new claims. There are a number of elements in the claims that are new matter.

For example, diagnostic methods involving a "double-flap" structure incorporate new matter. Claims 7-50 all involve diagnostic methods utilizing a "double-flap" structure. The specification, with or without the added text from the Harrington and Lieber reference, does not provide support for double-flap structures in diagnostic methods. Without the Harrington and Lieber reference, there is no support for "double-flap" structures at all. Even with the incorporation, there is no link between the "double-flap" structure shown in the figures of Harrington and Lieber, and the diagnostic methods contemplated in the '283 patent. In their amendment accompanying the reissue application, the Applicants point to two sections in their original application where the Harrington and Lieber reference was incorporated by reference. The first section, bridging columns 20-21 of the '283 patent, generically states that the reference is incorporated by reference, without pointing to any portion of the reference that is to be incorporated and without providing any context as to why the reference is being incorporated.[25] The second section, bridging columns 39-40 of the '283 patent, explains that

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[24] New matter may exist by virtue of the omission of a feature or of a step in a method (MPEP 1411.02).

[25] It is noted that mere mention of a reference is not an incorporation of anything into the application for the purpose of the disclosure required by 35 U.S.C. 112 (MPEP 608.01[p][I][a]). Particular attention should be directed to specific portions of the referenced document where the subject matter being incorporated may be found (MPEP 608.01[p][I][a]). Therefore, no consideration should be given to this first citation of the Harrington and Lieber reference.

"DNA flap substrates, cleavage and binding reactions, and the like" are practiced per the teaching of several references, including the Harrington and Lieber reference. This section simply provides instruction for studying FEN-1 endonuclease binding to flap structures (*i.e.*, basic research characterization of FEN-1 endonuclease binding and activity), rather than for any non-research uses (*e.g.*, diagnostic assays). The brief description of prophetic diagnostic methods in the '283 patent is found in the text bridging columns 42-43 and simply describes generic prior art methods utilizing a FEN-1 endonuclease. There is no contemplation of "double-flap" structures in this description. Indeed, the section is limited to single-flap structures.

Applicants may assert that the Harrington and Lieber reference is incorporated throughout the patent for the proposition that "double-flap" structures (*i.e.*, structures with a 3' and a 5' flap) are contemplated in every use. There are two problems with this argument. First, Applicants chose not to incorporate the Harrington and Lieber reference into the diagnostic section, but instead incorporated the reference only for the purpose of teaching methods for carrying out binding studies. Second, Applicants did not incorporate Harrington and Lieber alone, but in conjunction with several other references. Thus, in understanding the teachings of the incorporated references, the set of reference must be considered as a whole. It is relevant to note that two of the other incorporated references (Harrington and Lieber, *Genes and Development*, 8:1344-1355 [1994] and Harrington and Lieber, *The EMBO Journal*, 13:1235-1246 [1994]) teach that FEN-1 endonucleases are not useful with cleavage structures containing 3'-flaps (which "double-flap" structures have) or branched structures such as Holliday Junctions. Thus, collectively, there is no teaching or suggestion that one should use "double-flap" structures.

Claims 7-50 have many additional instances of new matter, even in view of the improperly amended specification. For example, Claim 7 recites the step of "selectively cleaving" the oligonucleotide containing the 5'-flap. There is simply no support for "selectively cleaving" anywhere in the application, with or without the incorporation of the Harrington and Lieber reference. Furthermore, Claim 7, and most of the dependent claims, are generic as to the cleavage means. This is new matter. There is no contemplation in the specification or the Harrington and Lieber reference of the cleavage of "double-flap" structures, or any other structure, with anything other than a eukaryotic FEN-1 endonuclease

(*see* definition for FEN-1, col. 13, lines 19-30). There is also no contemplation in the specification of any diagnostic method being carried out with anything other than a eukaryotic FEN-1 endonuclease (this is not surprising considering that invention of the original application was for specific mammalian FEN-1 endonucleases). Every sentence of the text describing the diagnostic methods in the '283 patent is limited to the use of eurkaryotic FEN-1 endonucleases (*See* Col. 42, line 64 to Col. 43, line 36).

Claims 21 and 36 are directed to methods of detecting the presence of a "target nucleic acid" in a "sample" where oligonucleotides containing a 3'-flap and 5'-flap are reacted with the target under conditions that allow the oligonucleotides to "specifically hybridize" to the target. This is new matter. The diagnostic description in the patent provides no support for "conditions" under which specific hybridization will occur to allow the detecting of a "target nucleic acid" in a "sample." Even **if** the Harrington and Lieber "double-flap" language was improperly added to the diagnostic description, there would still be no support for the claim language. The Harrington and Lieber experiments using a "double-flap" do not involve a target nucleic acid in a sample and do not provide conditions for specific hybridization where a target nucleic acid can be detected in a sample. For example, the teachings of the Harrington and Lieber reference for "conditions" for forming or using cleavage structures (citing Harrington and Lieber, EMBO Journal 13:1235 [1994]) are limited to complex formation conducted at 4°C, binding reactions conducted at 20°C, and cleavage assays conducted at 30°C. There is simply no teaching of conditions for conducting a diagnostic assay or support for the concepts of "specific hybridization" as claimed.

Many of the claims, including the new method claims, recite the concepts of "first portion"s and "second portion"s of a target nucleic acid in a double-flap cleavage structure and of "probe" oligonucleotide that are "immediately contiguous"[26] to one another on the "same target nucleic acid," or of "target-FEN-1 complexes" (Claim 36 and dependents). These items are all new matter. As discussed above, the double-flap structures in the Harrington and Lieber reference are not described in the context of a diagnostic assay or composition and are not incorporated into the '283 patent for these purposes. It appears that

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[26] The descriptions of the newly added figures also contain new matter. For example, new figure 8, 9A, 11 and 12 use the phrase "immediately contiguously", but this phrase does not appear in the Harrington and Lieber paper or the '283 patent.

Applicants are attempting to interpret aspects of certain figures in the Harrington and Lieber reference in an effort to apply them to diagnostic methods, *even though the figures in the paper have nothing to do with diagnostic methods.*

The Harrington and Lieber paper is silent on the concepts of "target nucleic acids" containing first and second regions and the like. This is made abundantly clear by looking at new dependent Claims 8 and 9. These claims include the elements of "detecting the presence of" a cleavage fragment from the cleaved double-flap structure to indicate "the presence of the target nucleic acid in the sample" and "quantifying the amount of nucleotide or polynucleotide released" where the quantity "correlates" with the "presence or abundance of the target nucleic acid in the sample." None of these concepts are taught in the Harrington and Lieber reference. Applicants will undoubtedly point to the diagnostic discussion of the '283 to argue for support for these concepts. However, this section does not contemplate the double-flap structures and provides no assay conditions (with or without the Harrington and Lieber reference) for conducting such assays with double-flap structures. One can't simply take words from one portion of a specification and combine them with words from an unrelated portion to weave together a new invention. The words of a patent do not exist in a vacuum. The teachings of the specification must be read as they are provided. As discussed throughout this protest, the portions incorporated by reference from Harrington and Lieber are not logically linked to the diagnostic methods. The inventors themselves never made this connection when the original application was filed and prosecuted. Thus, the introduction of these diagnostic double-flap concepts is new matter.

The remaining Claims 51-73 suffer from the same problems of new matter. These claims are directed to hybridization complexes having a "double-flap" structure and kits "for detecting the presence of a target nucleic acid in a sample" having oligonucleotides that form a "double-flap" structure. Thus, the analysis above applies to these claims as well. The only contemplated use for kits in the specification is for practicing diagnostic assays (col. 43 of the '283 patent). The description of kits does not incorporate the Harrington and Lieber reference and therefore does not contemplate "double-flap structures." Yet the kit claims incorporate specific diagnostic oligonucleotides comprising a double-flap structures. This is in complete disregard for the teachings of the kit description of the '283 patent. The kits contemplated by the '283 patent only include "a vial containing a substantially purified FEN-1." There is no

teaching AT ALL of the inclusion of any oligonucleotides in the kits, let alone oligonucleotides that form a double-flap structure.

The "hybridization complex" Claims 51-58 suffer from a similarly appalling lack of support and are equally riddled with new matter. There is no contemplation of "hybridization complexes" as an invention in either the specification of the '283 patent, or in the Harrington and Lieber reference. Indeed, the words "hybridization complex" do not even appear in the original or amended specification. Thus, the entirety of these claims is new matter.

The dependent claims introduce still further examples of new matter. For example, Claims 14-16, 31-33, 48-50, 56-58, and 62-64 all specify flap lengths on 3'- and 5'-probes in the context of diagnostic methods and compositions involving double-flap structures. Yet there is no explicit support for these ranges (and no indication that the claims would function within the scope of the claimed ranges). Once again, Applicants are, in hindsight, deconstructing figures from Harrington and Lieber and improperly applying certain aspects of the figures to diagnostic compositions and methods that have no link to the Harrington and Lieber teachings.

While the Applicants may argue that the matter added to the specification and claims is matter that was inherently found in the Harrington and Lieber reference, the MPEP cautions that "[d]epending on circumstances such as the adequacy of the *original* disclosure, the addition of inherent characteristics . . . may be new matter" (MPEP 608.04[a], *emphasis added*). In the present case the original disclosure is defective, providing no contemplation of the subject matter of the new claims and no indication that the inventors appreciated the "inventions" encompassed by the new claims (*see* Sections I and II of this protest). Therefore, there is no basis for arguing that the original disclosure inherently disclosed the new matter that has been added to the reissue application. Courts addressing such situations have clearly stated that "We recognize that the reissue provisions of the Patent Act should be construed liberally in light of their remedial purpose . . . but this liberality has never been construed to permit insertion of new matter in contravention of the § 251 proscription thereof. . . . The new matter provision of § 251 is thus a limit on the correction of errors . . . Where a patent is fatally defective, e.g., invalid for inadequate disclosure, such a defect cannot be cured by reissue seeking to put into the specification something required to be there when the application was originally filed." (*In re Hay*, 534 F.2d 917, 189 U.S.P.Q. 790 [CCPA 1976],

citations omitted). "So particular is the law on this subject that it is declared that 'no new matter shall be introduced into the specification.' This prohibition is general, relating to all patents; and by 'new matter' we suppose to be meant new substantive matter, such as would have the effect of changing the invention, or of introducing what might be the subject of another application for a patent. The danger to be provided against was the temptation to amend a patent so as to cover improvements which might have come into use, or might have been invented by others, after its issue." *Parker & Wipple Co. v. Yale Clock Co.*, 123 U.S. 87, 8 S.Ct. 38. (S.Ct. 1887).

CONCLUSION

The present reissue is so procedurally defective as to not warrant substantive review. The new patent owner's plan, *i.e.* to introduce alleged new inventions which the named inventors admit they didn't even recognize as their own, is a misuse of the reissue process. This is not a simple case of an attorney failing to understand the full scope of the invention - *this is a case of the INVENTORS failing to even recognize what is now brought before the Patent Office.* This is not "error" with respect to "the claims" - this is hindsight reconstruction of entirely new subject matter.

Moreover, the content of the new claims reveals complete disregard for the examination process. The new patent owners ignore the fact that the issued claims were i) elected in response to a restriction requirement - *a choice the applicants made without traverse* - and ii) narrowed down during the original prosecution to strictly cover specific nucleic acid sequences - *a choice the applicants made in order to overcome specific rejections by the Examiner.* The new claims are directed to non-elected and previously unclaimed subject matter and are drafted in many instances so as not to even limit the claim to the same genus (let alone species) of compounds. Indeed, some claims don't even include the originally claimed compounds (in any form or of any scope) as an element!

All of the new claims are unsupported by the original disclosure - and the improper importation of the contents of a referenced non-patent document does not solve this 112 problem. The claims contain terms utterly lacking in both the original specification and the amended specification. Finally, the new claims make combinations of elements without any

basis - picking elements from diverse parts of the original specification and combining them with selective portions of the improperly incorporated non-patent document.

Permitting the reissue to go forward would be improperly granting the new patent owners "a second opportunity to prosecute de novo his original application." *Nupla Corporation v. IXL Manufacturing Co., Inc.*, 114 F.3d 191 etc etc. (citing *In re Weiler* etc.etc.). This would open the door to any applicant who, in hindsight (years after the original filing), wants to completely avoid the consequences of a proper prosecution history. Indeed, such a free-for-all reissue process would render a prosecution history meaningless, resulting in the loss of all predictability of the patent process for the public. By contrast, refusing to i) recognize the alleged "error" offered by the new patent owners, and ii) examine the new claims directed to separate and distinct subject matter, is consistent with case law and MPEP guidelines, both of which were carefully drawn to ensure the fairness of the reissue remedy.

Dated: January 3, 2001

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APPENDIX A

In re Weiler, 790 F.2d 1576

790 F.2d 1576
229 U.S.P.Q. 673
(Cite as: 790 F.2d 1576)

United States Court of Appeals,
Federal Circuit.

In re Elmar W. WEILER and Richard L. Mansell.

Appeal No. 85-2085.

May 8, 1986.

Applicant appealed from a decision of the United States Patent and Trademark Office Board of Appeals, affirming an examiner's rejection of two patents claims in a reissue application. The Court of Appeals, Markey, Chief Judge, held that fact that subject matter of patent claims in question could be found somewhere in overall disclosure of patent did not entitle applicant to acceptance of such claims on patent reissue application, where applicant had failed to claim subject matter of such patent claims in original patent application, and subject matter of such patent claims was clearly independent of and distinct from each other, elected claims, and nonelected claims.

Affirmed.

West Headnotes

[1] Patents ⚿136
291k136

Federal statute, 35 U.S.C.A. § 251, governing reissue of defective patents, is remedial in nature, based on fundamental principles of equity and fairness, and should be construed liberally; nonetheless, not every event or circumstance that might be labeled "error" is correctable by reissue.

[2] Patents ⚿324.5
291k324.5

Court of Appeals reviews decisions, not mere language of an opinion; when that language indicates erroneous basis for decision, decision will be reversed.

[3] Patents ⚿141(3.1)
291k141(3.1)
(Formerly 291k141(3))

When reissue applicant seeks to obtain broadened version of claim in patent, one may look to see whether disclosure reasonably conveys to one skilled in art that inventor had possession of broad invention at time original application was filed. 35 U.S.C.A. § 251.

[4] Patents ⚿141(3.1)
291k141(3.1)
(Formerly 291k141(3))

Fact that subject matter of patent claims in question could be found somewhere in overall disclosure of patent did not entitle applicant for reissue to acceptance of such claims on patent reissue application, where applicant had failed to claim subject matter of such patent claims in original patent application, and subject matter of such patent claims was clearly independent of and distinct from each other, elected claims, and nonelected claims. 35 U.S.C.A. §§ 112, 251.

[5] Patents ⚿136
291k136

Phrase "intent to claim," which does not appear in 35 U.S.C.A. § 251, governing the reissue of defective patents, is but judicial shorthand, signifying means of measuring whether statutorily required error is present to reissue a defective patent.

[6] Patents ⚿136
291k136

Compliance with 35 U.S.C.A. § 112, setting forth requirements for patent specification, does not alone establish "intent to claim" and does not alone establish error in a failure to claim the subject matter of the reissue claim sought, for purposes of 35 U.S.C.A. § 251, governing the reissue of defective patents.

[7] Patents ⚿134
291k134

Federal statute, 35 U.S.C.A. § 251, governing the reissue of defective patents, was not enacted as panacea for all patent prosecution problems, nor as grant to patentee of second opportunity to prosecute de novo his original application.

[8] Patents ⚿141(6)
291k141(6)

Applicant, who accepted issuance of patent with its claims to a single elected invention and failed to file divisional applications on subject matter of nonelected

claims, foreclosed his right to claim that subject matter on application to reissue defective patent. 35 U.S.C.A. § 251.

Patents ⚖328(2)
291k328(2)

4,305,923. Cited.

*1577 William D. Stokes, Alexandria, Va., argued for appellants.

Richard E. Schafer, Associate Sol., U.S. Patent and Trademark Office, Arlington, Va., argued for appellee. With him on brief were Joseph F. Nakamura, Sol., and Fred E. McKelvey, Deputy Sol.

Before MARKEY, Chief Judge, and DAVIS and BISSELL, Circuit Judges.

*1578 MARKEY, Chief Judge.

Weiler and Mansell (Weiler) appeal from a decision of the United States Patent and Trademark Office Board of Appeals (board), App. No. 600-54 (Dec. 31, 1984), affirming the examiner's rejection of claims 13 and 19 in a reissue application filed under 35 U.S.C. § 251 (1982). We affirm.

Background

Weiler filed an application on May 8, 1980, containing 11 claims. During prosecution, the examiner held that the application contained "three independent and distinct inventions" and required restriction between Claims 1- 7 (assay method), Claims 8 and 11 (an "organic compound" in class 260/343.42), and Claims 9 and 10 (a "protein compound" in class 260/121). Weiler elected to prosecute Claims 1-7. Those claims were allowed without amendment, and the application issued on December 15, 1981 as U.S. Patent No. 4,305,923 ('923 patent) for a "Method for Quantitative Analysis for Limonin".

1. U.S. Patent No. 4,305,923

The seven claims of the patent are independent claim 1 and dependent claims 2- 7. Claim 1 reads:

> 1. A method for quantitative analysis of limonin which comprises reacting a known amount of limonin-specific antibodies, with a mixture of a known volume of sample containing an unknown amount of limonin and a known amount of a limonin-derivative labeled with an enzyme or with a radioactive isotope, determining the amount of labeled limonin-derivative which has reacted with said antibodies and calculating therefrom the unknown amount of limonin in said sample.

2. The Reissue Application

Weiler did not contest the examiner's requirement for restriction and did not file a divisional application, to assert the non-elected claims or any other claims.

On August 18, 1982, Weiler filed application Serial No. 408,497 to reissue the '923 patent. In his Declaration, Weiler said the '923 patent was partly inoperative or invalid by reason of his having claimed less than he had a right to claim, and that that deficiency "exists because of errors which were made without deceptive intent on my part."

Weiler alleged "an extraordinary sequence of events which preceded and followed the inadvertent abandonment of original claims 8-11" which made him aware that the invention of the '923 patent was not adequately claimed. His Declaration set forth: (1) a June 23, 1981 letter from patent attorney Earl Tyner to Manzell (co-inventor of the '923 invention) confirming Manzell's authorization to file a divisional application on claims 8-11; (2) Tyner's July 2, 1981 letter to Bryan Burgess (Office of General Counsel, University of Florida), about filing a divisional application; and (3) a January 19, 1982 letter to Mansell from Arthur Yeager, a partner in Tyner's firm, stating that a divisional application had not been filed.

The Declaration further stated that "on being made aware of the failure to timely file the divisional application," Mansell consulted with patent attorney William D. Stokes (counsel of record here), who drafted a set of claims which, he said in the Declaration, "should have been made in the original application."

3. The Reissue Claims

The reissue application contained 20 claims. Claim 13 reads:

> 13. A method for developing citrus fruit strains low in limonin content, which method comprises identifying by the use of limonin-specific antibodies as a analytical reagent the limonin-low mutants in a breeding or cell culture program, and propagating said mutants.

Claim 19 reads:

19. A gamma gobulin fraction comprising antibodies reactive with limonin, said antibodies being formed consequent *1579 to injecting into an animal a limonin-protein conjugate.

Claims 1-12 and 20 were allowed by the examiner. Claim 2 was cancelled by Weiler. Claims 13-19 were rejected, and that rejection was appealed to the board.

4. The Board's Action

The board agreed with the examiner's view that "failure to timely file a divisional application including non-elected claims is a deliberate act and not error in the prosecution of the original patent" (citing In re Orita, 550 F.2d 1277, 193 USPQ 145 (CCPA 1977)). It sustained the rejection of claims 14-18 on that ground, i.e., because they are "directed to the same subject matter as the non-elected conjugate claims 9 and 10" of the original application. Claims 14-18 are not before us on appeal.

The board sustained the rejection of claims 13 and 19 on this specific ground:

Appeal claims 13 and 19 are directed to subject matter not claimed at all in the original application. As to them, the Examiner's reliance on the case of In re Rowand et al. is entirely correct and that decision is controlling. Here, as in that case, "there is nothing in the original patent evidencing that appellants intended to claim (this now claimed subject matter)" (526 F.2d 558, 560, 187 USPQ 487 at 489).

Issue

Whether the board erred in sustaining the rejection of claims 13 and 19.

OPINION

Introduction

[1] The starting place is the statute itself, 35 U.S.C. § 251:

Whenever any patent is, through error without any deceptive intention, deemed wholly or partly inoperative or invalid, by reason of a defective specification or drawing, or by reason of the patentee claiming more or less than he had a right to claim in the patent, the Commissioner shall, on surrender of such patent and the payment of the fee required by law, reissue the patent for the invention disclosed in the original patent, and in accordance with a new and amended application, for the unexpired part of the term of the original patent. No new matter shall be introduced into the application for reissue.

In enacting the statute, Congress provided a statutory basis for correction of "error". The statute is remedial in nature, based on fundamental principles of equity and fairness, and should be construed liberally. In re Bennett, 766 F.2d 524, 528, 226 USPQ 413, 416 (Fed.Cir.1985) (in banc); Ball Corp. v. United States, 729 F.2d 1429, 1439 n. 28, 221 USPQ 289, 296 n. 28 (Fed.Cir.1984); In re Hay, 534 F.2d 917, 919, 189 USPQ 790, 791 (CCPA 1976). Nonetheless, not every event or circumstance that might be labeled "error" is correctable by reissue.

A. The Parties' Contentions

Weiler says the subject matter of neither claim 13 nor claim 19 constitutes "an independent and distinct invention" from that secured by the original patent, because both subject matters constituted part of the invention which was intended or sought to be secured by the original patent.

Pointing to the letters about a divisional application, on other claims, Weiler says his failure to claim the subject matter of claims 13 and 19 was not deliberate or purposeful, but was caused by the prosecuting attorney's error. He says that "but for the inventors' ignorance of patent drafting technique, their lack of knowledge of claiming technique, and their attorney's obvious lack of understanding of the invention, the subject matter of the part of the invention covered by claims 13 and 19 would have been included in the original patent."

The Solicitor's brief concedes that some minimal support for claims 13 and 19 appears in the patent's specification, but argues that "mere disclosure of this subject matter does not demonstrate an intent to *1580 claim this subject matter." The Solicitor's brief also argues that "if a mistake was made [in not filing a divisional application], it is not the type of mistake which can be corrected by reissue," citing In re Orita, 550 F.2d 1277, 1281, 193 USPQ 145, 149 (CCPA 1977). [FN1]

FN1. Because the rejection of claims 14-18 is not appealed, the parties' discussion of the reasons why Weiler failed to file divisional applications on the subject matter of those claims, Weiler's evidence consisting of letters about divisional applications on non-elected claims 8-11, and the Solicitor's reliance

on Orita, are irrelevant.

B. The Board's Opinion

In its opinion, the board said, as above indicated, that the subject matter of claims 13 and 19 "was not claimed at all in the original application" (emphasis added), and that nothing in the patent evidenced an "intent to claim" that subject matter, citing In re Rowand, 526 F.2d 558, 560, 187 USPQ 487, 489 (CCPA 1975), as controlling authority.

[2] This court reviews decisions, not the mere language of an opinion. When that language indicates an erroneous basis for the decision, the decision will be reversed, but that is not the case here. The board's language, while infelicitous, simply meant that Weiler's failure to have ever claimed, broadly or narrowly or otherwise, the subject matter of claims 13 and 19, and his failure to show an "intent to claim" that subject matter, indicated absence of the statutorily required "error."

The board's language reflected its well founded recognition that Weiler was seeking to claim subject matter entirely distinct from anything anywhere earlier claimed or attempted or intended to be claimed, and was not seeking to obtain a broadened or narrowed claim to subject matter claimed in the patent proffered for surrender. In dealing with that more common circumstance, one of our predecessor courts said "the whole purpose of the [reissue] statute, so far as claims are concerned, is to permit limitations to be added to claims that are too broad or to be taken from claims that are too narrow." In re Handel, 312 F.2d 943, 948, 136 USPQ 460, 464 (CCPA 1963).

C. Disclosure

Weiler argues, on the basis of loose language which, taken out of context, would appear to say that one looks only to see whether the subject matter of a reissue claim appears in the disclosure, and, if it does, a reissue applicant must be granted allowance of that claim. See D. Chisum, Patents, § 15.03[3] at 15-53 (1985); I. Kayton, Kayton on Patents, § 22-64 (1985). But the question of support in the disclosure is a § 112 inquiry. If there be no such support, the inquiry ends there, and reissue cannot be obtained. Thus, all consideration of § 251 must await that threshold § 112 determination. In the present case, as above indicated, there is some minimal support for the subject matter of claims 13 and 19.

[3][4] When, unlike the present case, a reissue applicant seeks to obtain a broadened version of a claim in the patent, one may look to see whether the disclosure "reasonably conveys to one skilled in the art that the inventor had possession of the broad invention at the time the original application was filed." In re Peters, 723 F.2d 891, 894, 221 USPQ 952, 954 (Fed.Cir.1984). That language speaks to the reason why the inventor failed to claim more broadly an invention he had claimed in the patent. It does not speak to the present case, in which Weiler did not claim the subject matter of the reissue claims "at all," to use the board's phrase. The language referring to the "disclosure" in Peters, and in other cases dealing with reissue, is directed ultimately to the question of error. One cannot assert error in failing to claim that which was not disclosed at all, or that which was not so disclosed as to indicate that the inventor was possessed of the invention as it is being claimed in the reissue application.

Weiler's argument that the subject matter of claims 13 and 19 does not constitute "an independent and distinct invention" ***1581** merely because that subject matter can be found somewhere in the overall disclosure of the '923 patent is meaningless. As above indicated, the subject matter must have been disclosed, § 112, or there is no basis for discussing whether the invention being claimed on reissue is independent or distinct. Moreover, § 251 authorizes reissue for "the" invention disclosed in the original patent, not for just "any" and "every" invention for which one may find some support in the disclosure of the original patent.

The subject matter of claims 13 and 19 are clearly independent of and distinct from each other, from that of elected claims 1-7, from that of non-elected organic compound claims 8 and 11, and from that of non-elected protein compound claims 9 and 10. Weiler would thus have had no right to insert and present claims 13 and 19 in the original application after the examiner's requirement for restriction.

Here too, the question redounds to one of error, for when an applicant makes some disclosure, as Weiler did, of as many as five distinct inventions, claims one, and ignores the rest, it is difficult to find error in the failure to claim those ignored on the sole basis that they were disclosed. To so hold would render meaningless the statutory requirement that an applicant point out and distinctly claim subject matter he regards as his invention. 35 U.S.C. § 112, 2d ¶. [FN2]

FN2. I. Kayton, Kayton on Patents, § 22-64 (1985) ("the predecessor to our present statute required that a reissue application be for 'the same invention' rather than for 'the invention disclosed' in the original patent ... Now it is only necessary to compare the reissue claims with the disclosure in the parent patent for the purpose of determining whether they are supported as required by 35 USC § 112" (emphasis in original)). As indicated in the text, compliance with § 112 is a threshold consideration, but such compliance does not establish error in a failure to claim every invention disclosed.

D. "Intent to Claim"

[5] Language appearing first in the opinion in U.S. Industrial Chemicals, Inc. v. Carbide & Carbon Chemicals Corp., 315 U.S. 668, 676, 62 S.Ct. 839, 843, 86 L.Ed. 1105, 53 USPQ 6, 9-10 (1942), has been picked up and has metamorphosed into a requirement that an applicant show his original "intent to claim" the subject matter of the reissue claim sought. The phrase "intent to claim" does not appear in the statute. It is but judicial shorthand, signifying a means of measuring whether the statutorily required error is present. Clearly, a showing that an applicant had an intent to claim matter he did not claim can go a long way to support a finding that error occurred; and, conversely, a showing that an applicant never had any such intent makes a finding of error extremely difficult if not impossible.

[6] References to "intent to claim" in our cases, though occasionally including § 112 considerations, resolve ultimately into the question of error. "Determining what protection [an inventor] intended to secure by [an] original patent for the purposes of § 251 is an essentially factual inquiry confined to the objective intent manifested by the original patent." In re Rowand, 526 F.2d 558, 560, 187 USPQ 487, 489 (CCPA 1975) (emphasis in original). As explained in a later decision, Rowand's test of "intent to claim" was not one of "intent" per se, but looked to "objective indicia of intent." In re Mead, 581 F.2d 251, 256, 198 USPQ 412, 417 (CCPA 1978). The court in Mead analogized that evidence of "intent" to the written description requirement of § 112, first paragraph, i.e., "a written description of the invention, and of the manner and process of making and using it." See also In re Peters, 723 F.2d 891, 894, 221 USPQ 952, 954 (Fed.Cir.1984). It is true that absence of compliance with § 112 will foreclose a finding of "intent" and preclude grant of the reissue, but, as indicated above, that absence dooms the application in any event. The converse is not true. Compliance with § 112 does not alone establish "intent to claim" and does *1582 not alone establish error in a failure to claim. [FN3]

FN3. One commentator has recently stated: "The intent test and the U.S. Industrial Chemicals statement [see text infra] are perhaps best understood as expressions of the 'description of the invention' requirement, which the Court of Customs and Patent Appeals recognizes as distinct from the enablement requirement." D. Chisum, Patents, § 15.03[3] at 15-53 (1985). The commentator could not have meant that compliance with § 112's enablement requirement is sufficient in itself to warrant an automatic finding of "intent" and a resulting reissue, in disregard of § 251's requirement to show error.

This court has recently moved the "intent to claim" approach toward closer conformity with the statute, describing it as merely one factor "that sheds light upon whether the claims of the reissue application are directed to the same invention as the original patent and the reissue would correct an inadvertent error in the original patent." In re Hounsfield, 699 F.2d 1320, 1323, 216 USPQ 1045, 1048 (Fed.Cir.1982) (emphasis added).

E. "Error"

[7] Thus, we arrive at the central question in this appeal, which is not whether there is disclosure, but whether Weiler has established "error" which can be remedied by reissue. The reissue statute was not enacted as a panacea for all patent prosecution problems, nor as a grant to the patentee of a second opportunity to prosecute de novo his original application.

The language of U.S. Industrial Chemicals, Inc. v. Carbide & Carbon Chemicals Corp., 315 U.S. at 676, 62 S.Ct. at 843, 53 USPQ at 9-10, is relevant here:

> [I]t is not enough that an invention might have been claimed in the original patent because it was suggested or indicated in the specification. It must appear from the face of the instrument that what is covered by the reissue was intended to have been covered and secured by the original. [Emphasis added.]

Weiler and the Solicitor argue as though the "error" to be corrected by reissue were a subjective error. It is not. We do not here deal with "deceptive intention".

Though the term "error" is to be interpreted liberally,

In re Wesseler, 367 F.2d 838, 84, 152 USPQ at 339, 348 (CCPA 1966), Congress did not intend to alter the test of "inadvertence, accident, or mistake" established in relation to the pre-1952 statutes. In re Wadlinger, 496 F.2d 1200, 1207, 181 USPQ 826, 831 (CCPA 1974). See In re Mead, 581 F.2d 251, 257, 198 USPQ 412, 418 (CCPA 1978) ("conscious choice" not to file continuing application not "error"); In re Clark, 522 F.2d 623, 626, 187 USPQ 209, 212 (CCPA 1975) (dereliction in duty of candor not "error"); In re Byers, 230 F.2d 451, 454, 109 USPQ 53 (CCPA 1956) (deliberate amendment of claim not "error"). See also In re Petrow, 402 F.2d 485, 159 USPQ 449 (CCPA 1968) (cancellation of claim in original application was "error"); In re Willingham, 282 F.2d 353, 127 USPQ 211 (CCPA 1960) (cancellation of claim was "error").

As above indicated, the discussions in the briefs concerning the failure to assert the non-elected claims in a divisional application are irrelevant. Those claims are not on appeal and were drawn to subject matter distinct from that of claims 13 and 19. Though Weiler might have filed a divisional application containing claims 13 and 19, there is nothing of record remotely indicating that Weiler or his counsel or anyone else ever thought of doing so, or ever intended doing so, or failed to do so only through error.

[8] Significantly, Weiler accepted issuance of the '923 patent with its claims to a single elected invention. By acquiescing in the examiner's restriction requirement, and failing to file divisional applications on the subject matter of non-elected claims, Weiler foreclosed (because that was not error) his right to claim that subject matter. If it were not error to forego divisional applications on subject matter to which claims had been made in the original application, it cannot on the present record have been error to forego divisional applications on subject matter to which claims had never been made. Nor has Weiler made any ***1583** showing on which error could be found as the cause of his failure to claim the subject matter of claims 13 and 19. [FN4]

> FN4. Weiler's reliance on allegations of the inventors' ignorance of drafting and claiming technique and counsel's ignorance of the invention is unavailing. Those allegations could be frequently made, and, if accepted as establishing error, would require the grant of reissues on anything and everything mentioned in a disclosure. Weiler supplies no facts indicating how the ignorance relied on caused any error as the basis of his failure to claim the subject matter of claims 13 and 19. As indicated in the text § 251 does not authorize a patentee to re-present his application. Insight resulting from hindsight on the part of new counsel does not, in every case, establish error.

The board's notation that the subject matter of claims 13 and 19 was "not claimed at all" in the original application, and its finding that nothing in the original patent evidences Weiler's "intent to claim" that subject matter, reflect non-statutory language used by courts and others to support and convey the concept that an inventor's failure to claim particular subject matter was not the result of the "error" required by § 251. Having made that notation and finding, the board should have stated the resulting basis (no error) for its decision. That it did not do so does not require reversal in this case, in which the record clearly supports the notation and finding, Weiler has not shown that either was clearly erroneous, and Weiler has shown nothing in the record that would have required the board to determine that his failure to claim the subject matter of claims 13 and 19 was the result of error.

AFFIRMED.

END OF DOCUMENT

tear strength in the range of 150-400 grams/mil.

34. An interpolymer of ethylene and from 1% to 20% by weight of a higher normal aliphatic olefinic hydrocarbon having 5 to 10 carbon atoms per molecule, said higher normal aliphatic olefinic hydrocarbon having no non-aromatic unsaturation other than one terminal -CH=CH$_2$ per molecule, said interpolymer having essentially no other copolymerized components, the proportion of the interpolymerized ethylene component therein being not less than 80% nor more than 99% by weight, the percentage of crystallinity of the interpolymer being such that the density ranges from 0.95 to 1% interpolymerized higher normal aliphatic olefinic hydrocarbon down to 0.9 at 20% interpolymerized higher normal aliphatic olefinic hydrocarbon, and the melt index of said interpolymer being within the range of 0.2 to 20, said interpolymer being further characterized by having in the form of a fabricated molding a stress crack resistance of greater than 1000 hours using an unnotched test specimen.

35. An interpolymer of ethylene and from 1% to 20% by weight of a higher normal aliphatic olefinic hydrocarbon having 5 to 10 carbon atoms per molecule, said higher normal aliphatic olefinic hydrocarbon having no non-aromatic unsaturation other than one terminal −CH=CH$_2$ per molecule, said interpolymer having essentially no other copolymerized components, the proportion of the interpolymerized ethylene component therein being not less than 80% nor more than 99% by weight, the percentage of crystallinity of the interpolymer being such that the density ranges from 0.945 down to 0.9, and the melt index of said interpolymer being within the range of 0.2 to 20, said interpolymer being further characterized by in wire coating form withstanding more than 1000 hours in air without failure in the Western Electric wire twist test.

36. An interpolymer of ethylene and from 1% to 20% by weight of a higher normal aliphatic olefinic hydrocarbon having 5 to 18 carbon atoms per molecule, said higher normal aliphatic olefinic hydrocarbon having no non-aromatic unsaturation other than one terminal -CH=CH$_2$ per molecule, said interpolymer having essentially no other copolymerized components, the proportion of the interpolymerized ethylene component therein being not less than 80% nor more than 99% by weight, the percentage crystallinity of the interpolymer being such that the density ranges from 0.95 at 1% interpolymerized higher normal aliphatic olefinic hydrocarbon down to 0.9 at 20% interpolymerized higher normal aliphatic olefinic hydrocarbon, said interpolymer having a melt index within the range of 0.2 to 20, and said interpolymer being further characterized by in pipe form withstanding 3000 hours at hoop stress of 750 psi and a temperature of 60°C.

37. An interpolymer of ethylene and from 1% to 20% by weight of a higher normal aliphatic olefinic hydrocarbon having 5 to 14 carbon atoms per molecule, said higher normal aliphatic olefinic hydrocarbon having no non-aromatic unsaturation other than terminal -CH=CH$_2$ per molecule, said interpolymer having essentially no other copolymerized components, the proportion of the interpolymerized ethylene component therein being not less than 80% nor more than 99% by weight, the percentage crystallinity of the interpolymer being such that the density ranges from 0.95 at 1% interpolymerized higher normal aliphatic olefinic hydrocarbon down to 0.9 at 20% interpolymerized higher normal aliphatic olefinic hydrocarbon, said interpolymer having a melt index within the range of 0.2 to 20, and said interpolymer being further characterized by having in film form an Elmendorf tear strength in the range of 150-140 grams/mil.

38. An interpolymer of ethylene and from 1% to 20% by weight of a higher normal aliphatic olefinic hydrocarbon having 5 to 18 carbon atoms per molecule, said higher normal aliphatic olefinic hydrocarbon having no non-aromatic unsaturation other than one terminal -CH=CH$_2$ per molecule, said interpolymer having essentially no other copolymerized components, the proportion of the interpolymerized ethylene component therein being not less than 80% nor more than 99% by weight, the percentage crystallinity of the interpolymer being such that the density ranges from 0.95 at 1% interpolymerized higher normal aliphatic olefinic hydrocarbon down to 0.9 at 20% interpolymerized higher normal aliphatic olefinic hydrocarbon, said interpolymer having a melt index within the range of 0.2 to 20, and said interpolymer being further characterized by having in the form of a fabricated molding a stress crack resistance of greater than 1000 hours using an unnotched test specimen.

39. An interpolymer of ethylene and from 1% to 20% by weight of a higher normal aliphatic olefinic hydrocarbon having 5 to 18 carbon atoms per molecule, said higher normal aliphatic olefinic hydrocarbon having no non-aromatic unsaturation other than one terminal -CH=CH$_2$ per molecule, said interpolymer having essentially no other copolymerized components, the proportion of the interpolymerized ethylene component therein being not less than 80% nor more than 99% by weight, the percentage crystallinity of the interpolymer being such that the density ranges from 0.945 down to 0.9, said interpolymer having a melt index within the range of 0.2 to 20, and said interpolymer being further characterized by in wire coating form withstanding more than 1000 hours in air without failure in the Western Electric wire twist test.

40. An interpolymer having impact strength or environmental stress crack resistance properties that are superior to those obtained with comparable free-radical polyethylenes, liner polyethylenes, interpolymers of ethylene and propylene and interpolymers of ethylene and butene, said interpolymer being an interpolymer of ethylene and from 1% to 20% by weight of 4-methyl-1-pentene, said interpolymer having essentially no other copolymerized components, the proportion of the interpolymerized ethylene component therein being not less than 80% nor more than 99% by weight, the percentage crystallinity of the interpolymer being such that the density ranges from about 0.95 at 1% interpolymerized 4-methyl-1-pentene down to about 0.9 at 20% interpolymerized 4-methyl-1-pentene, the melt index of said interpolymer being within the range of 0.2 to 20.

41. Composition of claim 19, wherein said higher olefinic hydrocarbon is n-decene-1.

Court of Appeals, Federal Circuit

In re Amos

No. 91-1298

Decided December 31, 1991

PATENTS

1. Practice and procedure in Patent and Trademark Office — Reissue — Same invention (§110.1305)

Practice and procedure in Patent and Trademark Office — Reissue — Broader claims sought (§110.1313)

Board of Patent Appeals and Interferences erred by rejecting reissue claims on ground that applicants lacked objective intent to claim subject matter of new claims at time of original application, and that applicants' failure to claim subject matter was therefore not result of "error" required by 35 USC 251, since rejection under "original patent" clause of Section 251 requires finding that person skilled in art would not, from reading of specification, identify subject matter of reissue claims as invented and disclosed by patentees, and since board specifically found that subject matter of reissue claims had been disclosed in accordance with 35 USC 112; absence of intent to claim subject matter of reissue claims, even if objectively evident from original claims, drawings, or original objects of invention, does not constitute independent ground for denying reissue application.

Particular patents — General and mechanical — Hold down device

4,610,582, Amos, Greathouse, and Riddle, roller hold down device, rejection of claims 10-12 in application for reissue reversed.

Appeal from the U.S. Patent and Trademark Office, Board of Patent Appeals and Interferences.

Application of James R. Amos, Chester K. Greathouse, and David S. Riddle, for broadened reissue of patent no. 4,610,582, issued Sept. 9, 1986 (roller hold down device). From decision upholding rejection of reissue claims 10-12, applicants appeal. Reversed.

Marvin Moody, of Hill, Van Santen, Steadman & Simpson, Chicago, Ill., for appellants.

Lee E. Barrett, associate solicitor (Fred E. McKelvey, solicitor, with him on brief), for Commissioner of Patents and Trademarks.

Before Mayer, Lourie, and Clevenger, circuit judges.

Clevenger, J.

James R. Amos, Chester K. Greathouse, and David S. Riddle (collectively, "patentees") submitted an application for a broadened reissue of U.S. Patent No. 4,610,582 ("582 patent"). New claims 10 through 12 were finally denied after appeal to the Board of Patent Appeals and Interferences ("Board") of the U.S. Patent and Trademark Office ("PTO") because the "failure to claim the subject matter of claims 10 through 12 was not the result of the 'error' required by 35 USC 251" since the "objective intent of the patentees" had been to claim only the subject matter in the already issued claims. *In re Amos*, No. 90-3019, slip op. at 8 (BOPAI Feb. 27, 1991). We reverse because the objective intent of the patentees cannot, alone, form the basis for a denial of reissue claims.

I

The 582 patent, which issued on September 9, 1986, claims a set of rollers mounted to hold down a workpiece laid upon a moving table until the end of the table is reached, whereupon the rollers lift away from the table surface. The rollers are designed to lift away so that they cannot fall off the end of the table. 582 patent, col. 1, ln. 15-28, col. 4, claims 1-9. The specification contemplates that lifting will occur automatically:

> As the rollers approach the end of the table travel the outside roller is raised either mechanically by the roller cams or electronically by the computer controlling the router. This action prevents the roller from falling off the table and then being damaged as the table moves back against the outside roller.

582 patent, col. 3, ln. 61, col 4, ln. 2 (reference numbers deleted).

The original claims were not directed to the alternative of using a computer to control the lifting of the rollers. Less than one year after issuance and thus within the statutory time permitted for broadened reissue, the patentees filed a declaration with the PTO that they believed "the original patent to be through error, without deceptive intention, wholly or partly inoperative and invalid for the reason that we claimed less than we had a right to claim in not including claims of the scope of newly submitted claims 10, 11 and 12 which are directed to the concept of controlling the rollers and clamps by the computer." The examiner objected to the declaration because the patentees had not "specif[ied] the errors relied upon, and how they arose or occurred" as expressly required by 37 C.F.R. § 1.175(a)(5) (1988). The Manual of Patent Examining Procedure, at § 1414.03 illustrates the scope of the regulatory provision, by stating, in part:

> It is particularly important that the reissue oath or declaration specify in detail how the errors arose or occurred. . . . If the reissue oath or declaration does not particularly specify "how," i.e., the manner in which the errors arose or occurred, the Office will be unable to adequately evaluate reissue applicant's statement in compliance with § 1.175(a)(6) that the "errors arose 'without deceptive intention' on the part of the applicant"; see § 1414.04.

Thereafter, the patentees submitted a supplemental declaration which, in pertinent part, averred:

> How this error arose is as follows. Due to mistake and inadvert[e]nce during the preparation of the original application which resulted in [the 582 patent], the attorney who drafted the original claims did not include due to oversight any claims to the combination of the computer for the router which may be connected to control the rollers and the clamps to automatically release them. . . .
>
> After September 9, 1986 when U.S. Patent issued, the inventors asked for an opinion as to whether the allowed claims in U.S. Patent covered a combination for a computer for router which may be connected to control the rollers and the clamps to automatically release. As soon as such request was received, the attorney for applicants studied the issued claims of [the 582 patent] and gave the opinion to the inventors that such combination of the computer was not covered by the issued claims. The inventors then instructed the attorney to prepare and file this reissue application with claims to the computer embodiment.

Supplemental Reissue Declaration at ¶ 4 (reference numbers deleted).

Nonetheless, the examiner finally rejected claims 10-12 because the declaration failed "to particularly specify how the errors relied upon arose or occurred, as required under 37 CFR 1.175(a)(5)." Office Action in U.S. Application Ser. No. 056,784 from PTO Examiner to the patentees (Oct. 17, 1988) at 2. Furthermore, the examiner rejected the claims because they were not "for the same invention as that disclosed as being the invention in the original patent," asserting that this was required by 35 U.S.C. § 251. The examiner stated that there was no "evidence that applicant considered the use of the router computer to control the rollers and the clamps to be their invention." *Id.* (citing *In re Mead*, 581 F.2d 251, 198 USPQ 412 (CCPA 1978)). We read, as did the Board, the examiner's final rejection to be based upon both of two independent prerequisites to reissue, found in 35 U.S.C. § 251, which are that the patentee specify "error without any deceptive intention" and that the Commissioner may not reissue a patent with new claims unless the reissued patent is "for the invention disclosed in the original patent." On the patentees' appeal to the Board, the examiner filed an answer which contended that, additionally, the "disclosure fails to present an enabling disclosure on which claims 10-12 can find support" as required by 35 U.S.C. § 112 ¶ 1.

II

In its opinion, the Board first addressed the examiner's finding that the reissue declaration was legally insufficient under 37 C.F.R. § 1.175(a)(5) for failing to specify or identify the type of error contemplated by the statute. The Board held:

> Our assessment of the supplemental reissue declaration, however, indicates to us that it complies with 37 CFR 1.175(a)(5). Specifically, we determine that section 4) of the supplemental declaration, bridging pages 2 and 3 thereof, particularly specifies in reasonable detail how the errors relied upon arose by setting forth a chronology of relevant events.

In re Amos, slip op. at 4.

The Board further found that "the subject matter of these claims was disclosed in accordance with 35 USC 112." *Id.* at 8. However, the Board concluded that:

> appellants' failure to claim the subject matter of claims 10 through 12 was not the result of the "error" required by 35 USC 251. The subject matter of claims 10 through 12 was not originally claimed, not an object of the original patent, and not depicted in the drawing. Thus, we perceive that the *objective intent* of the patentees manifested in the original patent was to solely claim the invention of claim 1 through 9.
>
> * * *
>
> Specifically, appellants submit that there is no manifestation of an *intent* not to claim in the original patent, and argue that the patent clearly shows that they *intended to claim* the control of the rollers and clamps by the computer. The difficulty we have with this advocated position is that appellants do not provide us with any insight as to where the original disclosure evidences an *intent to claim*, and we can find none.
>
> In summary, this board sustains the examiner's rejection of appellants' claims under 35 USC 251, for the reasons given above.

In re Amos, slip op. at 8-9 (emphasis added).

The Board thus specifically declined to affirm the rejection on two of the grounds suggested by the examiner: that the disclosure did not support the claims under § 112 ¶ 1; and, that the supplemental affidavit did not satisfy the statutory requirement that reissue is permitted only upon demonstration of error without any deceptive intention. Rather, the Board found that the disclosure of the original patent failed to set forth an "intent to claim" the subject matter for which protection was sought on reissue.

III

This appeal invites us to address the proper role under 35 U.S.C. § 251, if any, for the concept of an "intent to claim" in a rejection of claims submitted during reissue. We start, as we must, with the words of the statute, which, in pertinent part, state:

> Whenever any patent is, through error without any deceptive intention, deemed wholly or partly inoperative or invalid, by reason of a defective specification or drawing, or by reason of the patentee claiming more or less than he had a right to claim in the patent, the Commissioner shall, on the surrender of such patent and the payment of the fee required by law, reissue the patent for the invention disclosed in the original patent, and in accordance with a new and amended application, for the unexpired part of the term of the original patent. No new matter shall be introduced into the application for reissue.

35 U.S.C. § 251 ¶ 1 (1988).

The section requires that the patentee base the application for reissue upon one of four specified grounds statutorily-identified as correctable defects. *In re Clark*, 522 F.2d 623, 625-26, 187 USPQ 209, 211-12 (CCPA 1975). First, an asserted defect may arise from an error in the specification. *In re Salem*, 553 F.2d 676, 679, 193 USPQ 513, 516 (CCPA 1977) (reissue permitted to correct specification term "polyvalent anions" to clearly-implied "source of polyvalent anions"). Second, the patentee may correct a defective drawing. The final two reasons for which the patentee may seek reissue concern original claims subsequently discovered to have been either too narrow or too broad. *In re Handel*, 312 F.2d 943, 948, 136 USPQ 460, 464 (CCPA 1963) (purpose of statute is to permit limitations to be added to, or removed from, claims). The basis for seeking narrowing reissue has generally been the belated discovery of partially-invalidating prior art. *In re Harita*, 847 F.2d 801, 805, 6 USPQ2d 1930, 1932 (Fed. Cir. 1988). In contrast, a broadened reissue has generally been founded upon post-issuance discovery of attorney error in understanding the scope of the invention. *In re Wilder*, 736 F.2d 1516, 1519, 222 USPQ 369, 371 (Fed. Cir. 1984) ("attorney's failure to appreciate the full scope of the invention is one of the most common sources of defects"), *cert. denied*, 469 U.S. 1209 (1985); *see also Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565, 1575, 18 USPQ2d 1001, 1009 (Fed. Cir. 1991).

In setting forth the purpose of the reissue, the patentee must submit an oath or declaration along with the surrendered patent and a payment of the requisite fee. 37 C.F.R. § 1.172(a) (1988); *see* 35 U.S.C. § 251 ¶ 3 (1988). "There are two distinct statutory

requirements that a reissue oath or declaration must satisfy. First, it must state that the patent is defective or partly inoperative or invalid because of defects in the specification or drawing, or because the patentee has claimed more or less than he is entitled to. Second, the applicant must allege that the defective, inoperative, or invalid patent arose through error without deceptive intent." *Wilder*, 736 F.2d at 1518, 222 USPQ at 370; *see also Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 882 F.2d 1556, 1564-65, 11 USPQ2d 1750, 1757-58 (Fed. Cir. 1989), *cert. denied*, 110 S.Ct. 1125 (1990).

Finally, the statute restricts the Commissioner to reissuing the patent only "for the invention disclosed in the original patent" with the proviso that "[n]o new matter shall be introduced into the application." The "original patent" clause of § 251 creates a requirement that precludes reissue, historically styled as a "same invention" rejection, of patents with claims to subject matter that could not have been claimed in the original patent that is submitted for reissue.

As is apparent from the foregoing statutory analysis, "[t]he phrase 'intent to claim' does not appear in the statute." *In re Weiler*, 790 F.2d 1576, 1581, 229 USPQ 673, 676 (Fed. Cir. 1986); *see also Scripps Clinic*, 927 F.2d at 1575, 17 USPQ2d at 1009 ("'Intent to claim' is not the criterion for reissue").

IV

In practice, the rejection of reissue claims has been founded upon either a failure to demonstrate error without deceptive intention, *see Weiler*, or because the newly submitted claims are not supported by the disclosure of the "original patent." In the decision before us, the Board specifically rejected the examiner's contention that the supplementary declaration was insufficient to demonstrate "error without any deceptive intention."[1] Thus, we do not read the Board opinion as having rejected the claims because the submitted declaration failed to specify the statutorily-required error.

Thus, we must read the Board's invocation of the "infelicitous" phrase, "intent to claim," *see Weiler*, 790 F.2d at 1580, 229 USPQ at 675, as a decision that the new claims were not "for the invention disclosed in the original patent," or, in the time-honored terminology, were not for the "same invention." We note that the phrase has been oft employed in support of a rejection grounded upon a failure of the patentee to show that the new claims are directed to the "same" invention as that originally disclosed. *In re Rowand*, 526 F.2d 558, 187 USPQ 487 (CCPA 1975); *In re Mead*, 581 F.2d 251, 198 USPQ 412 (CCPA 1978). Therefore, the Board's decision must be based upon its determination that the original disclosure does not support the subject matter of the new claims as required by the "original patent" clause of § 251.

We thus must turn to our binding precedent from the Court of Customs and Patent Appeals to understand the legal parameters that support a "same invention" or "original patent" rejection of claims in a reissue application. As noted by that court:

> "intent to claim" arose from the requirement that the reissue be for the "same invention" as the original, i.e., that it cover what was "intended to have been covered" by the original [citing 35 U.S.C. § 64 (1946), *repealed by* Patent Act of 1952, Pub. L. No. 593, § 251, 66 Stat. 792, 808 (1952)]. . . .
>
> * * *
>
> Thus, in *Rowand* and similar cases, "intent to claim" has little to do with "intent" *per se*, but rather is analogous to the requirement of § 112, first paragraph that the specification contain a "written description of the invention, and of the manner and process of making and using it." It is, as appellant urges, synonymous with "right to claim."

Mead, 581 F.2d at 256, 198 USPQ at 417.

Our predecessor court further explained the proper test under the "same invention" or "original patent" statutory arm:

> Determining what protection appellants intended to secure by their original patent for the purposes of § 251 is an essentially factual inquiry confined to the *objective* intent manifested by the original patent.

Rowand, 526 F.2d at 560, 187 USPQ at 489 (emphasis original).

Hence, the purpose of the rubric "intent to claim" is to ask the same question as to whether "new matter" has been "introduced into the application for reissue" thus, perforce, indicating that the new claims are not drawn to the same invention that was originally disclosed. That inquiry is but a restatement of the question whether that which is claimed in reissue could have been claimed on the basis of the original disclosure, given that the requisite inadvertent error has been demonstrated, as is the case here. Thus, the inquiry that must be undertaken to determine whether the new claims are "for the invention" originally disclosed, to paraphrase *Rowand*, is to examine the entirety of the original disclosure and decide whether, through the 'objective' eyes of the hypothetical person having ordinary skill in the art, an inventor could fairly have claimed the newly submitted subject matter in the original application, given that the requisite error has been averred. We agree with, and, in any event, are bound by, the statement in *Mead*, quoted above, that the inquiry under § 251 as to whether the new claims are for the invention originally disclosed is analogous to the analysis required by § 112 ¶ 1. Under one aspect of that analysis, a court must ascertain whether "the disclosure originally filed [conveys] to those skilled in the art that applicant had invented the subject matter later claimed." *Wilder*, 736 F.2d at 1520, 222 USPQ at 372; *see also In re Kaslow*, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed. Cir. 1983); *In re Edwards*, 568 F.2d 1349, 1351, 196 USPQ 465, 467 (CCPA 1978) ("The function of the description requirement is to ensure that the inventor had possession, as of the filing date of the application relied on, of the specific subject matter later claimed by him.").

Since the Board concluded that the original disclosure embraces the matter claimed in reissue, the Board erred in denying the reissue application on the basis of the lack of an "intent to claim." In the case at hand, the Solicitor, in his brief to this court, expressly concedes that the Board was correct in finding that the patentees' reissue claims comply with the enablement and written description requirements of § 112 ¶ 1. Under *Rowand*, given a satisfactory averment of inadvertent error, this position is arguably inconsistent with a "same invention" rejection. However, the issue of whether the tests, for written description and enablement under § 112 ¶ 1 and for "same invention" under § 251, are in every case exactly co-extensive, neither briefed nor argued in this case, is not properly before us on the instant facts, since the Board's decision rests only upon the factual determination that the patentees' lacked an objective "intent to claim" the new subject matter. We need only decide whether a reissue application can be rejected under the "error" rubric for failure to demonstrate an objective intent to claim, when the Board has held that the subject matter of the reissue claims meets the requirements of § 112 ¶ 1.

[1] We conclude that, under both *Mead* and *Rowand*, a claim submitted in reissue may be rejected under the "original patent" clause if the original specification demonstrates, to one skilled in the art, an absence of disclosure sufficient to indicate that a patentee could have claimed the subject matter. Merely finding that the subject matter was "not originally claimed, not an object of the original patent, and not depicted in the drawing," does not answer the essential inquiry under the "original patent" clause of § 251, which is whether one skilled in the art, reading the specification, would identify the subject matter of the new claims as invented and disclosed by the patentees. In short, the absence of an "intent," even if objectively evident from the earlier claims, the drawings, or the original objects of the invention is simply not enough to establish that the new claims are not drawn to the invention disclosed in the original patent.[2]

Our conclusion in this circumstance is dictated by this Court's previous decision in *In re Hounsfield*, 699 F.2d 1320, 216 USPQ 1045 (Fed. Cir. 1983).[3] In *Hounsfield*, the Solicitor, in his brief on behalf of the Board, expressly conceded that the Board was incorrect in finding that the patentees' reissue claims complied with the enablement and written description requirements of § 112 ¶ 1. Neither party nor the Board cited or discussed this case. Inexplicably, all three rely instead on dicta from *Weiler*. The issue for decision in *Weiler* was whether the patentee had demonstrated error without deceptive intention, not whether the claims were to the same invention as the "original patent." We do not quibble with the holding in *Weiler* that satisfaction of the § 112 ¶ 1 written description requirement does not establish "error" under § 251. *Weiler*, 790 F.2d at

[1] In its brief on behalf of the Board, the Solicitor argues in the alternative that the Board clearly erred in determining that the declaration was sufficient to satisfy the statutory requirement of error without deceptive intention. Assuming, *arguendo*, that the Solicitor's office can challenge the decision of its client, we do not agree. The Board's decision that the supplementary declaration averred sufficient facts to support a finding of error is not clearly erroneous.

[2] The Solicitor cites the case of *U.S. Industrial Chems. v. Carbide & Carbon Chems. Corp.*, 315 U.S. 668 [53 USPQ 6] (1942), in support of the Board's use of the phrase "intent to claim." In *U.S. Industrial*, the Supreme Court held that the reissue claims were invalid because the patentees had added new matter to the original disclosure which was the only support for those claims. In the course of the decision, which was based upon the statutory requirement that the reissue claims be for the "same invention," *see* 35 U.S.C. § 64 (1946), the Supreme Court referred to various other tests under which reissue claims might be held invalid. To the extent that the language of *U.S. Industrial* supports the use of the legal oxymoron, "objective intent to claim," as an analytical tool to discern the scope of the original disclosure, nothing in this opinion, nor in *Mead*, *Rowand*, or *In re Hounsfield*, 699 F.2d 1320, 216 USPQ 1045 (Fed. Cir. 1983), differs in legal significance. The objective intent to claim found in the original disclosure, insofar as the construct is analytically useful, however, exists as "only one factor that sheds light upon whether the claims in the reissue application are directed to the same invention as the original patent and the reissue would correct an inadvertent error in the original patent." *Hounsfield*, 699 F.2d at 1323, 216 USPQ at 1048.

Board rejected reissue claims on the ground that " 'the record makes it clear that it was not appellant's intention to claim the subject matter of claims 7 through 11 in the original [131] patent.' " *Hounsfield*, 699 F.2d at 1321, 216 USPQ at 1046 (quoting the Board). The issue for decision was whether the rejection was sustainable under § 251. This Court concluded that:

> lack of "intent to claim" is not an independent basis for denying a reissue application under section 251. It is only one factor that sheds light upon whether the claims of the reissue application are directed to the same invention as the original patent and the reissue would correct an inadvertent error in the original patent.

Hounsfield, 699 F.2d at 1323, 216 USPQ at 1048.

Thus, we conclude, as did this Court in *Hounsfield*, that the presence or absence of an objective intent to claim, standing alone, is simply not dispositive of any required inquiry under § 251.

REVERSED

Court of Appeals, Federal Circuit

The Laitram Corp. v. NEC Corp.

No. 91-1108

Decided December 31, 1991

PATENTS

1. Practice and procedure in Patent and Trademark Office — Re-examination — In general (§110.1501)

Practice and procedure in Patent and Trademark Office — Re-examination — Prior art considered (§120.1505)

Infringement — Defenses — Prosecution history estoppel (§120.1105)

Any amendment to claim during re-examination following rejection based on prior art does not automatically mean that claim has been substantively changed as matter of law and does not create per se estoppel; rather, to determine whether claim change is substantive, claims of original and re-examined patents must be analyzed in light of particular facts, including prior art, prosecution history, other claims, and any other pertinent information.

JUDICIAL PRACTICE AND PROCEDURE

2. Procedure — Summary judgment — Patents (§410.3303)

Interpretation of patent claims is question of law, but summary disposition is nevertheless improper if it is necessary to resolve disputed issues of fact in course of interpreting claims.

Particular patents — Electrical — Printing systems

3,952,311, Lapeyre, electro-optical printing system, grant of partial summary judgment of non-infringement reversed.

Appeal from the U.S. District Court for the Eastern District of Louisiana, McNamara, J.; 17 USPQ2d 1407.

Action by The Laitram Corp. against NEC Corp., NEC Information Systems Inc., and Sears, Roebuck and Co. for patent infringement. From grant of partial summary judgment in favor of defendants, plaintiff appeals. Reversed and remanded.

Timothy J. Malloy, of McAndrews, Held & Malloy, Chicago, Ill. (Larence M. Jarvis, Gregory J. Vogler, and Jean Dudek Kuelper, Chicago, on brief; Phillip A. Wittman and Steven Usdin, of Stone, Pigman, Walther, Wittmann & Hutchinson, New Orleans, La.; Barry L. LaCour and Mark T. Drapanas, Harahan, La., of counsel), for appellant.

John M. Calimafde, of Hopgood, Calimafde, Kalil, Blaustein & Judlowe, New York, N.Y. (Marvin N. Gordon, Charles Quinn, and David H. Kagan, New York, on brief; James D. McMichael, of Liskow & Lewis, New Orleans, La., of counsel), for appellees.

Before Newman, Archer, and Rader, circuit judges.

Newman, J.

In a suit for patent infringement filed by The Laitram Corporation against NEC Corporation, NEC Information Systems, Inc., and Sears, Roebuck and Company (collectively "NEC"), the grant of partial summary judgment in favor of NEC was certified for immediate appeal.[1]

The question raised is whether amendments made to patent claims during reexamination of the patent are substantive as a matter of law, when the amendments are made following a rejection based on prior art. We conclude that there is no *per se* rule. It must be determined whether the claims are substantively changed, on consideration of the facts of the case.

Accordingly, the grant of partial summary judgment is reversed. The case is remanded for further proceedings.

Background

United States Patent No. 3,952,311 (the '311 patent) entitled "Electro-Optical Printing System", inventor James M. Lapeyre, was issued on April 20, 1976 and is assigned to the Laitram Corporation. The patent is directed to high speed electro-optical printing, whereby printed characters are produced on a sheet of radiation sensitive material. As described in the specification, radiation emitting elements are arrayed in a straight line and the radiation sensitive material is moved past the emitter array at constant speed, in a direction perpendicular to the line of the array. As the radiation sensitive material moves past the array, certain of the emitters are activated so as to produce type quality alpha-numeric characters.

A request for reexamination was filed by a third party, not involved in this suit. The patent examiner determined that the request raised a substantial new question of patentability[2] as to claims 1 and 2, the only claims of the original '311 patent. During the ensuing reexamination the examiner rejected claims 1 and 2 on the ground of obviousness, 35 U.S.C. §103, in view of certain newly cited references. Claim 2 was also rejected as anticipated, 35 U.S.C. §102(b), by one of the newly cited references.

Laitram filed a response in which it amended claims 1 and 2, and added new claims 3 through 27 containing additional limitations. Claims 1 and 2 follow, wherein the words added during reexamination are italicized and the words deleted are shown in brackets:

> 1. An electro-optical printing apparatus for printing *type quality* alpha-numeric characters *at high speed* on a surface of a photosensitive recording material, said apparatus comprising:
>
> a plurality of *rapidly reacting* radiation emitters each being capable of emitting radiation at wavelengths to which said surface is sensitive, said emitters being disposed in an array along a substantially straight line, said array being a plurality of rows of said radiation emitters;
>
> means for moving said recording material *in a single direction substantially perpendicular to said straight line* with its surface adjacent said array, and at a substantially constant speed relative to said array and;
>
> means for selectively activating each of said emitters for predetermined periods of time, and
>
> means for coordinating the predetermined period of time in which each of the said plurality of emitters are activated with said constant relative speed of said recording material so that the radiation emitted by said emitters will be recorded on selected areas of said recording surface in the form of an alpha-numeric image,
>
> each of said emitters being positioned to irradiate a different area of said recording surface, the different areas of said surface irradiated by each of the said emitters being arranged in an overlapping relationship with one another *and said plurality of emitters being of sufficient number to print said type quality alpha-numeric characters.*
>
> 2. A method of electro-optically printing *type quality* alpha-numeric characters *at high speed* on the recording surface of a photosensitive material, said method comprising the steps of:
>
> arranging a plurality of *rapidly reacting* radiation emitters in a straight line array, each of the said emitters being capable of emitting radiation at wavelengths to which said photosensitive material is sensitive,

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1581 n.2, 229 USPQ at 676 n.2. *Weller* did not involve the question of whether § 112 ¶ 1 speaks conclusively to the "original patent" requirement of § 251. *See* 4 D. Chisum *Patents* § 15.03 [3] n.15 (1991). We have no ready explanation for the Board's or the parties' attention to *Weller* and utter inattention to *Hounsfield*.

[1] *Laitram Corp. v. NEC Corp.*, 17 USPQ2d 1407 (E.D. La. 1990), *certification ordered*, No. 89-1571 (October 11, 1990), *petition for permission to appeal granted*, Misc. No. 291 (Fed. Cir. Nov. 20, 1990). Jurisdiction in this court is pursuant to 28 U.S.C. §1292(c) (1).

[2] 35 U.S.C. §303.

> (a) Within three months following the filing of a request for reexamination under the provisions of section 302 of this title, the Commissioner will determine whether a substantial new question of patentability affecting any claim of the patent concerned is raised by the request, with or without consideration of other patents or printed publications. . . .

48 U.S.P.Q.2d 1225
157 F.3d 1340, 1998-2 Trade Cases P 72,289
(Cite as: 48 U.S.P.Q.2d 1225)

C.R. Bard Inc.
v.
M3 Systems Inc.

U.S. Court of Appeals Federal Circuit

No. 96-1165

Decided September 30, 1998

United States Patents Quarterly Headnotes

PATENTS
[1] Patentability/Validity -- Anticipation -- Identity of elements (Section 115.0704)
Verdict that patent claims for biopsy needles are invalid for anticipation is unsupported by substantial evidence, since claimed needles differ from prior art needles in flange structure for coupling needles to biopsy "gun" for movement both toward and away from housing, which is structure that limits all claims, as well as in additional limitation in two claims requiring slit in stylet head flange.

PATENTS
[2] Patentability/Validity -- Obviousness -- Combining references (Section 115.0905)
Verdict that invention of patent for biopsy needles was obvious in view of prior art is unsupported by evidence, since no prior art provided suggestion or motivation to make needle assembly with structure shown and claimed in patent, and since absent this essential evidentiary component of obviousness holding, verdict of invalidity on that ground cannot stand as matter of law.

PATENTS
[3] Practice and procedure in Patent and Trademark Office -- Certificate of correction -- Correction of named inventor (Section 110.1205)
Practice and procedure in Patent and Trademark Office -- Reissue -- In general (Section 110.1301)
Evidence does not support verdict holding patent invalid on ground that correction of inventorship was improperly made by reissue, since prosecution history shows that error in inventorship was described in reissue application and corrected by appropriate petition, filed and processed while reissue application was pending, since petition to correct inventorship may be filed during reissue proceedings, and since error in inventorship was corrected before reissue patent was granted.

PATENTS
[4] Practice and procedure in Patent and Trademark Office -- Reissue -- In general (Section 110.1301)
Primary purpose of reissue statute is to enable addition of claims to subject matter not claimed in original patent, and inventor's failure to appreciate scope of invention at time of original patent grant, and thus initial intent not to claim omitted subject matter, is remediable error.

PATENTS
[5] Patentability/Validity -- Specification -- Written description (Section 115.1103)
Claims for biopsy gun requiring "sequential energizing" of biopsy needles cannot be held invalid on ground that written description does not describe how to obtain elimination of all overlap of needle movement, since claims must be construed in accordance with rest of specification, not contrary to it, since specification illustrates sequential energizing of needles as having some overlap in movement, since no usage or exemplification of sequential movement in patent requires elimination of all overlap, and since correct interpretation of claims thus allows for slight overlap in needle movement; it is incorrect to construe claims in manner contrary to specification and then hold claims invalid because they are unsupported by written description.

PATENTS
[6] Patentability/Validity -- Obviousness -- Combining references (Section 115.0905)
Invention of patent for biopsy gun providing mechanical "sequential energizing" or cocking of its two biopsy needles was not obvious over combination of plaintiff's prior biopsy guns, which allowed for sequential manual cocking and mechanical, simultaneous cocking respectively, since no cited reference suggests structure employed in gun of patent, or mechanical sequential energizing, or other features of claimed gun.

PATENTS
[7] Infringement -- Literal infringement (Section 120.05)
Patent construction -- Claims -- Means (Section 125.1307)
Means plus function claims of patent for biopsy gun providing mechanical "sequential energizing" or cocking of its two biopsy needles are not infringed by

accused devices, even though accused guns also perform function of sequential energizing, since claimed structure employing rotational tensioning as energizing means is substantially different from energizing structure in accused gun; existence of other claims in patent which specifically state structure does not warrant finding that "means" claims at issue are not limited to structure in specification, since means-plus- function limitation is not made open-ended by presence of other claims specifically claiming disclosed structure which underlies means clause or equivalent of that structure.

PATENTS

[8] Practice and procedure in Patent and Trademark Office -- Prosecution -- Duty of candor -- Materiality (Section 110.0903.04)

There is no presumption that information not filed by patent applicant was material simply because patentability ensued, since, to establish culpability for fraud in procurement of patent, any omission must be of fact material to patentability, and it must be deliberate misrepresentation, whether by omission or misstatement, that was intended to and did mislead examiner into taking favorable action that would not otherwise have been taken; intent to deceive or mislead must be established by clear and convincing evidence, and deceptive intent is not inferred simply because information was in existence that was not presented to examiner.

PATENTS

[9] Patent misuse -- Federal antitrust issues (Section 140.07)

There is no presumption that patent-based right to exclude necessarily establishes market power in antitrust terms, since virtually unlimited variety and scope of patented inventions and market situations militate against per se rules; unless patent had been obtained by fraud such that market position had been gained illegally, patent right to exclude does not constitute monopoly power prohibited by Sherman Act.

PATENTS

[10] Patent misuse -- Improper procurement and enforcement (Section 140.03)

Patent misuse -- Federal antitrust issues (Section 140.07)

Judgment finding antitrust violation cannot be sustained on ground that patentee used fraudulently obtained patent to restrain competition, since establishing liability on such ground requires showing that patent was fraudulently procured, that patentee's related commercial activity was coupled with violations of Sherman Act's Section 2, and that patentee had specific intent to monopolize, engaged in anti-competitive conduct, and had dangerous probability of success, and since, in view of incorrect verdicts of fraud in procurement of patents in suit, judgment cannot be sustained as matter of law.

PATENTS

[11] Patent misuse -- Improper procurement and enforcement (Section 140.03)

Patent misuse -- Federal antitrust issues (Section 140.07)

Law recognizes presumption, overcome only by affirmative evidence of bad faith, that assertion of duly granted patent is made in good faith, since, absent showing that lawsuit is objectively meritless, and that suit conceals attempt to interfere directly with competitor's business relationships, patentee must have right to enforcement of duly granted patent, unencumbered by punitive consequences should patent's validity or infringement not survive litigation; judgment finding antitrust violation in present case cannot be upheld on "sham" litigation grounds, since infringement defendant failed to present substantial evidence that litigation was objectively meritless and brought in bad faith.

PATENTS

[12] Patent misuse -- Improper procurement and enforcement (Section 140.03)

Judgment on verdicts finding patent misuse must be reversed, since there was no evidence that infringement plaintiff's competitive activities were either per se patent misuse or that they were not "reasonably within the patent grant," since conduct to which jury instruction on misuse generally referred, namely attempt to enforce patents against goods known not to be infringing, is not subject to collateral attack as new ground of "misuse," in that it is not patent misuse to bring suit to enforce patent rights not fraudulently obtained, and since verdicts thus are not supported by evidence or correct legal theory.

PATENTS

[13] Patent misuse -- Federal antitrust issues (Section 140.07)

Judgment on jury verdict finding antitrust violation based on patentee's modification of biopsy gun to prevent use of competing replacement needles is affirmed, since evidence was sufficient to support jury's specific finding that patentee enjoyed monopoly

power in market for replacement needles, and its conclusion that patentee maintained its monopoly position by exclusionary conduct; although patentee contended at trial that it modified gun in order to make it easier to load and unload, there was substantial evidence that patentee's real reasons for modification were to raise cost of entry to potential replacement needle makers, to make doctors apprehensive about using competitors' needles, and to preclude use of "copycat" needles.

PATENTS

Particular patents -- General and mechanical -- Biopsy guns

4,944,308, Akerfeldt, tissue sampling device, judgment of invalidity reversed; judgment of non-infringement affirmed.

Re. 34,056 (of 4,699,154), Lindgren and Akerfeldt, tissue sampling device, judgment of invalidity affirmed; judgment of non-infringement vacated.

***1227** Appeal from the U.S. District Court for the Northern District of Illinois, Bucklo, J.

Action by C.R. Bard Inc. against M3 Systems Inc. for patent infringement, in which defendant asserted claims for fraud, violation of antitrust laws, and patent misuse. From judgment for defendant on all issues, plaintiff appeals. Affirmed in part, reversed in part, vacated in part, and remanded.

Opinion for the court by Judge Newman except for Part I.E (on-sale issue) and Part VI.C (attempt to monopolize). Judge Bryson does not join Parts I.A-D of Judge Newman's opinion. The district court's judgment concerning the on-sale bar is affirmed in separate opinions by Chief Judge Mayer and Judge Bryson. The district court's judgment concerning the attempt to monopolize issue is reversed in part by Judge Newman's opinion (Parts VI.A-B), which Chief Judge Mayer and Judge Bryson join, and affirmed in part by Judge Bryson's opinion (Part II), which Chief Judge Meyer joins. Judge Newman dissents with respect to the on-sale bar and attempt to monopolize issues.

Related decisions: 34 USPQ2d 1474 ; 32 USPQ2d 1535 .

John F. Sweeney, Harry C. Marcus, Desiree M. Stahl, Walter G. Hanchuk, Warren H. Rotert, and Steven F. Meyer, of Morgan & Finnegan, New York, N.Y., for plaintiff-appellant.

Richard D. Harris, Max Shaftal, Jordan A. Sigale, and Jovan N. Jovanovic, of Dick & Harris, Chicago, Ill.; Paul E. Slater and Greg Shinall, of Sperling, Slater & Spitz, Chicago, for defendant-appellee.

Before Mayer, chief judge, and Newman and Bryson, circuit judges. Newman, J.

In suit are United States Patent No. 4,944,308 issued July 31, 1990 (the '308 patent) and United States Reissue Patent No. RE 34,056 issued September 8, 1992 (the '056 patent), both entitled "Tissue Sampling Device." These patents originated with the work of Dr. Per Gunner Lindgren, a physician in Sweden, and are now owned by appellant C.R. Bard, Inc.

The patented inventions are devices for taking samples of body tissue for biopsy purposes, wherein a biopsy needle firing device or "gun" mechanically injects a biopsy needle assembly into the core body tissue. These devices are described as improving the speed, accuracy, ease, and patient comfort of tissue sampling, compared with manually inserted biopsy needles. They are said to be particularly advantageous for sampling small or movable lesions and fibrous or firm tissues, because the rapidly and firmly fired needles can penetrate even fibrotic lesions before the lesions can slip aside. The patented guns and needles have achieved commercial success.

Bard sued M3 Systems in August 1993 in the United States District Court for the Northern District of Illinois, [FN1] asserting that M3's ProMag biopsy gun and ACN/SACN biopsy needle assemblies infringed the '308 and '056 patents, respectively. M3 raised the defenses that the patents are invalid on several grounds and are not infringed, and also charged Bard with fraud, antitrust law violation, and patent misuse. The jury rendered special verdicts in favor of M3 on every issue, finding the '056 patent invalid and not infringed on each of the grounds of anticipation, obviousness, violation of a section 102(b) bar, incorrect naming of inventors, and non-compliance with reissue requirements; and finding the '308 patent invalid and not infringed on grounds of anticipation, obviousness, and insufficient written description. The jury also found that Bard perpetrated fraud in the Patent and Trademark Office (PTO) in obtaining both patents, that Bard misused both patents, and that Bard violated antitrust law, awarding $1.5 million in antitrust damages, trebled by the

district court.

The district court denied all post-trial motions. This appeal followed. This court affirms the judgment of invalidity of the '056 patent and vacates the judgment of noninfringement of the '056 patent. The judgment of invalidity of the '308 patent is reversed and the judgment of noninfringement is affirmed. The judgments of misuse and fraud are reversed. The judgment of antitrust violation on the ground of attempt to monopolize is affirmed, but the antitrust damages award is vacated, for redetermination upon remand.

*1228 THE PATENTED INVENTIONS

The First Generation Device -- The PCT Patent Application

In 1981 Dr. Lindgren, working in Sweden with Jan Allard, an engineer, designed and constructed the first of several successively improved mechanical biopsy guns. This "first generation" gun was designed to fire a commercially available biopsy needle assembly made by the Baxter Travenol Company, having the brand name "Tru-Cut." The Tru- Cut is a double needle consisting of a hollow outer needle called the cannula and an inner needle called the stylet. The stylet is solid except for a recess near its point. In the manual procedure for which the Tru-Cut was designed, the physician would first extend the stylet and insert the assembly into the body tissue, whereupon the tissue to be sampled would flow into the recess in the stylet; the physician would then push the cannula into the body tissue to surround the stylet and cut and trap the tissue sample in the recess.

This procedure required the physician to use both hands to manipulate the needles, while a second physician would hold and manipulate the ultrasound equipment that is usually required to view the interior of the body and direct insertion of the needles. Dr. Lindgren sought to mechanize this procedure in order to improve the speed and accuracy of insertion, to reduce human error, and to permit a physician to perform the biopsy without assistance by providing a sampling device that can be operated with one hand while the other hand holds the ultrasound apparatus.

The first generation gun is a box-like structure fitted with two spring- loaded drivers associated with slots that are configured to hold the cannula and stylet of the Tru-Cut needle assembly. To use this gun the physician must first "cock" each of the spring- loaded drivers. This cocking action, as it was often called at trial, is referred to as pre-tensioning or energizing in the patent documents. Cocking is performed by hand or with a specially designed tool described as a miniature crowbar. After the drivers are cocked, the stylet and cannula are placed in the appropriate slots and the gun housing is closed. The gun is then aimed at the target tissue and a trigger mechanism releases the stylet and cannula in rapid sequence. The needles are then manually retrieved.

Dr. Lindgren and Mr. Allard filed a patent application on the first generation gun under the Patent Cooperation Treaty (PCT). The invention was assigned to Radiplast AB, a small Swedish company associated with Dr. Lindgren. The PCT application was filed on March 31, 1982 and was published on October 13, 1983. It is prior art to the United States patents in suit.

The Second Generation -- The '056 Reissue Patent

Starting in 1984, Dr. Lindgren undertook to improve the gun so that it would not be necessary for the physician to cock the two drivers manually before installing the biopsy needles, a step described as awkward and inefficient. In 1985 Dr. Lindgren, working with Dan degrees Akerfeldt, an engineer, designed a mechanism whereby the drivers are cocked by external action after the needles are placed in the gun and the housing is closed. In this mechanism rods are attached to each of the spring-loaded drivers, extend out the back of the gun, and culminate in a ring or handle. By pulling the ring or handle the operator simultaneously cocks both drivers, moving the needles rearward. A trigger mechanism then fires the stylet and cannula, in rapid sequence, into the tissue to be sampled.

The Tru-Cut needles were not usable with the second generation gun, for their structure was such that they could not be moved rearward as well as propelled forward. New needles were designed with a modified hub and flange structure and a slit in the stylet flange to facilitate placement in the gun. Corresponding structural changes were made to the gun to accommodate the changes in the needles. Radiplast, as assignee, filed a patent application in Sweden on February 19, 1986. The United States application was filed on July 30, 1986, naming Dr. Lindgren as the inventor. Corresponding United States Patent No. 4,699,154 (the '154 patent) was issued on October 13, 1987, with claims to the

combination of the second generation gun and the new needle assembly. The ' 154 patent did not claim the needle assembly alone.

In 1989 Bard, having become Radiplast's distributor in 1987, acquired ownership of the Radiplast patents. Bard applied for reissue of the '154 patent in order to add claims to the needle assembly alone. This reissue patent issued on September 8, 1992, and is the '056 patent in suit. During the reissue proceeding Bard and Dr. Lindgren petitioned the PTO to correct the inventorship to include Dan degrees Akerfeldt. In addition, Bard described to the PTO various activities of Radiplast in the United States, as shall be discussed in connection with the on-sale issue.

***1229** The Third Generation Gun -- The '308 Patent

Dan degrees Akerfeldt continued to work on improving these devices. He sought to make the gun easier to use, especially by inexperienced physicians. Because pulling the cocking ring required significant manual force to overcome the simultaneous resistance of both driver springs, he designed an external integrated cocking mechanism that energized the two springs sequentially, thereby requiring less force than did the simultaneous cocking mechanism of the second generation gun. The third generation gun also provided for separate rearward movement of the needles after the biopsy sample was taken, thereby facilitating removal of the tissue from the stylet. Radiplast applied for a United States patent on the third generation gun on November 14, 1988, naming Dan degrees Akerfeldt as inventor. The patent issued in 1990 and ispatentthe '308 in suit.

I

VALIDITY OF THE '056 REISSUE PATENT

Bard charged M3 Systems with infringement of claims 9-12 and 21-23 of the ' 056 patent. M3 had the burden of establishing invalidity by clear and convincing evidence at trial. Carella v. Starlight Archery, 804 F.2d 135, 138, 231 USPQ 644, 646 (Fed. Cir. 1986). On review, the appellate court must "decide for ourselves whether reasonable jurors viewing the evidence as a whole could have found the facts needed to support the verdict in light of the applicable law."Lemelson v. General Mills, Inc., 968 F.2d 1202, 1207, 23 USPQ2d 1284, 1288 (Fed. Cir. 1992). The appellant must establish that the jury's actual or inferred factual findings were not supported by substantial evidence, or that the found or inferred facts were not sufficient to support the conclusion, or that the law was incorrectly applied. See, e.g., Applied Med. Resources Corp. v. United States Surgical Corp., 147 F.3d 1374, 1376, 47 USPQ2d 1289, 1290 (Fed. Cir. 1998); D.M.I., Inc. v. Deere & Co., 802 F.2d 421, 425, 231 USPQ2d 276, 278 (Fed. Cir. 1986).

When a claim or defense can not be maintained or defeated without a favorable finding on a material issue, and there is not substantial evidence supporting that finding, the verdict can not stand and the court must render judgment as a matter of law. See Fed. R. Civ. P. 50; Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 251-52 (1986); see generally Markman v. Westview Instruments, Inc., 52 F.3d 967, 975, 34 USPQ2d 1321, 1326 (Fed. Cir. 1995) (in banc), aff'd, 517 U.S. 370, 38 USPQ2d 1461 (1996). The appellate court must determine whether on the evidence of record a jury might properly have returned a verdict in the non-movant's favor when the correct legal standard is applied. If not, the movant was entitled to have the question removed from the jury and decided as a matter of law.

We apply these principles to each of the grounds on which the jury rendered verdicts of invalidity of the asserted '056 claims. We direct our discussion of validity primarily to claim 21, for the claim is representative and M3 Systems' expert witnesses admitted infringement of claim 21 by M3's original ACN needles:

21. A biopsy needle for use with a tissue sampling device having a housing with a forward end, a first slide mounted for longitudinal motion within said housing, and a second slide mounted for longitudinal motion within said housing, said biopsy needle comprising:

a hollow first needle having proximal and distal ends;

a second needle extending through said hollow first needle and freely slidable therewithin, said second needle having proximal and distal ends;

a first head mounted to said proximal end of said hollow first needle, said first head including first flange means associated therewith for coupling said hollow first needle to said first slide for longitudinal motion both toward and away from said forward end

of said housing; and

a second head mounted to said proximal end of said second needle, said second head including second flange means associated therewith for coupling said second needle to said second slide for longitudinal motion both toward and away from said forward end of said housing.

A. Anticipation

To meet the requirements of patentability a device must be new; that is, it must not have been previously known. Section 102(a) requires that the subject matter was not published anywhere, or known or used by others in the United States, before its invention by the patentee. [FN2] An invention that ***1230** does not meet the requirements of novelty in section 102(a) is said to be "anticipated."

When the defense of lack of novelty is based on a printed publication that is asserted to describe the same invention, a finding of anticipation requires that the publication describe all of the elements of the claims, arranged as in the patented device. Shearing v. Iolab Corp., 975 F.2d 1541, 1544-45, 24 USPQ2d 1133, 1136 (Fed. Cir. 1992); Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir 1989); Perkin-Elmer Corp. v. Computervision Corp., 732 F.2d 888, 894, 221 USPQ 669, 673 (Fed. Cir. 1984). The jury found that all of the claims at issue were "fully anticipated by a single prior art reference." Bard states that no reference described the new biopsy needle assembly of the '056 patent, and that the closest prior art, which all agree is the Travenol Tru-Cut needle assembly, differs in material ways. M3 Systems states that the Tru-Cut (or a publication describing the Tru-Cut) anticipated the claimed needle assembly because the '056 claims, correctly construed, read on the Tru-Cut.

The district court declined to construe all of the claim terms that were placed in dispute, instructing the jury that "words in a claim are to be given their ordinary and accustomed meaning, unless it appears that the inventor intended to use them differently. . . . You may use the specification to interpret what the patentee meant by a word or phrase in a claim." The record shows that the court defined some terms and the parties explained their views to the jury. This procedure was not incorrect at the time this case was tried -- for as the court observed, the question of the relative roles of judge and jury was then before the Supreme Court -- and does not of itself warrant a new trial. On appellate review, however, we apply the principles of Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1454-56, 46 USPQ2d 1169, 1172-75 (Fed. Cir. 1998) (in banc), and determine whether on the correct claim construction the jury verdict can stand. SeeEthicon, Inc., 103 F.3d 1554, 1568, 41 USPQ2d 1225, 1236 (Fed. Cir.)United States Surgical Corp. v. (reviewing whether the verdict reached was in accordance with correct claim construction), cert. denied, 118 S. Ct. 369 (1997).

1. The Term "Freely Slidable"

M3 Systems contends that the claim term "freely slidable" does not distinguish the '056 claims from the Tru-Cut needle assembly. The term "freely slidable" appears in the following claim clause:

a second needle extending through said hollow first needle and freely slidable therewithin, . . .

Bard argues that the court should have construed "freely slidable" for the jury, and that correctly construed this term means that the needle slides freely in either direction. M3 responds that Bard improperly seeks to insert the limitation "totally" into the definition of "freely slidable" and that, correctly construed, "freely slidable" requires only sliding freely in the forward direction. M3 states that since the Tru-Cut is freely slidable in the forward direction, the claim reads on the prior art and is invalid for anticipation.

M3 Systems' proposed claim construction is not correct, and could not have reasonably been adopted. The specification leaves no uncertainty that the '056 needles are freely slidable in both directions, for that is a purpose of the new '056 needle structure. M3's proposed interpretation is unsupported by, and indeed is contrary to, the specification. See Slimfold Mfg. Co. v. Kinkead Indus., Inc., 810 F.2d 1113, 1116, 1 USPQ2d 1563, 1566 (Fed. Cir. 1987) (claims are not interpreted "in a vacuum," but are read and understood in light of the specification of which they are a part). The jury's finding of anticipation can not be sustained if grounded on M3's interpretation of "freely slidable," for it was not disputed that the prior art Tru-Cut needles can not slide in both directions.

2. The "Housing"

M3 Systems argues that the preamble of the '056 claims refers only to the "housing" of the tissue sampling device, and that the lack of any preamble reference to an external automatic cocking mechanism invalidates the claims by anticipation because they fail to distinguish the gun of the preamble from the prior art first generation gun.

M3 Systems has incorrectly construed the claim preamble. A preamble may serve a variety of purposes, depending on its content. It may limit the scope of the claim, for example when patentability depends on limitations stated in the preamble, as in In re Stencel, 828 F.2d 751, 754, 4 USPQ2d 1071, 1073 (Fed. Cir. 1987), or when the preamble contributes to the definition of the claimed ***1231** invention, as in Bell Communications Research, Inc. v. Vitalink Communications Corp., 55 F.3d 615, 620, 34 USPQ2d 1816, 1820 (Fed. Cir. 1995). In this case, however, the preamble simply states the intended use or purpose of the invention, as in Loctite Corp. v. Ultraseal Ltd., 781 F.2d 861, 868, 228 USPQ 90, 94 (Fed. Cir. 1985). Such a preamble usually does not limit the scope of the claim unless the preamble provides antecedents for ensuing claim terms and limits the claim accordingly. In Vaupel Textilmaschinen KG v. Meccanica Euro Italia S.P.A., 944 F.2d 870, 880, 20 USPQ2d 1045, 1053 (Fed. Cir. 1991), for example, the preamble described a "reference point" that provided guidance in understanding and construing the claim.

In the case at bar, the preamble of claim 21 recites the portion and structure of the gun housing into which the needles fit, and provides reference points in the gun that aid in defining the needles as set forth in the body of the claim. M3 Systems is incorrect in stating that the preamble must contain details of the integrated mechanical cocking structure, for the gun structure is not part of the separate claims to the needles. The question of anticipation of the '056 claims relates to the needles, not the gun. To the extent that the jury verdicts of anticipation may have been based on M3's incorrect construction of the preamble, they can not be sustained. On the correct construction of the preamble, it contributes no basis of invalidity on the ground of anticipation.

3. The On-sale Bar and "Anticipation"

M3 Systems defends these anticipation verdicts by arguing that the asserted claims are anticipated because they are subject to an on-sale bar. Although 35 U.S.C. Section 102(b) provides that an inventor's sales or offers of sale more than one year before the patent filing date may bar the grant of a valid patent, [FN3] the on-sale bar is an independent ground of invalidity based on the inventor's delay in entering into the patent system. Although the on-sale bar can arise from one's own invention, "anticipation" does not arise from sale of one's own invention. We discuss the on-sale issue post; however, this aspect is unrelated to the "anticipation" verdicts, was not part of the jury instruction on that issue, and is not based on correct law.

Conclusion

[1] In sum, M3 Systems directs us to no prior art or prior knowledge or use by others that constitutes substantial evidence of anticipation of the needles claimed in the '056 patent. M3's witnesses conceded that the '056 needles differ from the Tru-Cut in the flange structure for coupling to the gun for movement both toward and away from the housing, a structure that limits all claims, as well as in the additional limitation in claims 10 and 12 of a slit in the stylet head flange. It is not disputed that the Tru-Cut needle assembly lacks these elements. In view of these admitted differences between the '056 needles and the prior art, differences unambiguously stated in the '056 claims, the verdicts of anticipation are unsupported by substantial evidence. The judgment of invalidity on this ground is reversed.

B. Obviousness

Invalidity based on obviousness is a question of law based on underlying facts. See Graham v. John Deere Co., 383 U.S. 1, 17-18, 148 USPQ 459, 467 (1966); Panduit Corp. v. Dennison Mfg. Co., 810 F.2d 1561, 1566-68, 1 USPQ2d 1593, 1595-97 (Fed. Cir. 1987). The relevant facts relate to (1) the scope and content of the prior art, (2) the level of ordinary skill in the field of the invention, (3) the differences between the claimed invention and the prior art, and (4) any objective evidence of nonobviousness such as long felt need, commercial success, the failure of others, or copying. Graham, 383 U.S. at 17, 148 USPQ at 467 ; see Continental Can Co. USA, Inc. v. Monsanto Co., 948 F.2d 1264, 1270, 20 USPQ2d 1746, 1750-51 (Fed. Cir. 1991).

The ultimate determination of obviousness vel non is a legal conclusion. See Ashland Oil, Inc. v. Delta

Resins & Refractories, Inc., 776 F.2d 281, 297 n.24, 227 USPQ 657, 667 n.24 (Fed. Cir. 1985). When a patent describes a new mechanical device that can be viewed as a new combination or arrangement of mechanical components, the legal conclusion of obviousness requires that there be some suggestion, motivation, or teaching in the prior art whereby the person of ordinary skill would have selected the components that the inventor selected and used them to make the new device. See Heidelberger Druckmaschinen AG v. Hantscho Commercial Prods., Inc., 21 F.3d 1068, 1072, 20 USPQ2d 1377, 1379 (Fed. Cir. 1993) ***1232** ("When the patented invention is made by combining known components to achieve a new system, the prior art must provide a suggestion or motivation to make such a combination."); Northern Telecom, Inc. v. Datapoint Corp., 908 F.2d 931, 934, 15 USPQ2d 1321, 1323 (Fed. Cir. 1990) (it is insufficient that prior art shows similar components, unless it also contains some teaching, suggestion, or incentive for arriving at the claimed structure). We review a jury verdict of obviousness to determine whether substantial evidence supports the factual findings predicate to the legal conclusion of obviousness and whether such findings can support the verdict, with appropriate consideration of the presumption of validity and the requirement that obviousness be proved by clear and convincing evidence; factual inferences are drawn and credibility determinations are accepted in favor of the verdict winner. See Richardson- Vicks Inc. v. Upjohn Co., 122 F.3d 1476, 1480, 44 USPQ2d 1181, 1183-84 (Fed. Cir. 1997); Structural Rubber Prod. Co. v. Park Rubber Co., 749 F.2d 707, 718-19, 223 USPQ 1264, 1273 (Fed. Cir. 1984).

M3 Systems argued at trial that the patented needle assembly would have been obvious in light of the Tru-Cut needle assembly, and that the only differences arose from obvious adaptations to accommodate the new gun design and to provide the desired reverse movement of the needles. No other prior art was presented. The invention that was made, however, does not make itself obvious; that suggestion or teaching must come from the prior art. See, e.g., Uniroyal, Inc. v. Rudkin-Wiley Corp., 837 F.2d 1044, 1051-52, 5 USPQ2d 1434, 1438 (Fed. Cir. 1988) (it is impermissible to reconstruct the claimed invention from selected pieces of prior art absent some suggestion, teaching, or motivation in the prior art to do so); Interconnect Planning Corp. v. Feil, 774 F.2d 1132, 1143, 227 USPQ 543, 551 (Fed. Cir. 1985) (it is insufficient to select from the prior art the separate components of the inventor's combination, using the blueprint supplied by the inventor); Fromsom v. Advance Offset Plate, Inc., 755 F.2d 1549, 1556, 225 USPQ 26, 31 (Fed. Cir. 1985) (the prior art must suggest to one of ordinary skill in the art the desirability of the claimed combination).

[2] No prior art provided a teaching or suggestion or motivation that a needle assembly should be made with the structure shown and claimed in the ' 056 patent. Absent this essential evidentiary component of an obviousness holding, as a matter of law the verdicts of invalidity on that ground can not stand. Consequently, the judgment of invalidity based on obviousness is reversed.

C. Inventorship

The jury rendered special verdicts of invalidity of the asserted '056 claims on the ground of incorrect inventorship. Inventorship is a question of law, applied to relevant facts. Findings of relevant fact are reviewed on the standard appropriate to the trier of fact, in this case for substantial evidence. See Hess v. Advanced Cardiovascular Sys., Inc., 106 F.3d 976, 980, 41 USPQ2d 1782, 1786 (Fed. Cir.), cert. denied, 117 S. Ct. 2459 (1997). The application of law to the found or admitted facts is reviewed on appeal without deference to the trier of fact. See Ethicon, Inc. v. United States Surgical Corp., 135 F.3d 1456, 1460, 45 USPQ2d 1545, 1547 (Fed. Cir. 1998); Sewall v. Walters, 21 F.3d 411, 415, 30 USPQ2d 1356, 1358 (Fed. Cir. 1994).

The "inventor," in patent law, is the person or persons who conceived the patented invention. Collar Co. v. Van Dusen, 90 U.S. (23 Wall.) 530, 563-64 (1874); Burroughs Wellcome Co. v. Barr Lab., Inc., 40 F.3d 1223, 1227-18, 32 USPQ2d 1915, 1919 (Fed. Cir. 1994) ("Conception is the touchstone of inventorship.") Thus facts relevant to inventorship are those showing the conception of the invention, for others may provide services in perfecting the invention conceived by another without becoming an "inventor" by operation of law. Id.; Agawam Co. v. Jordan, 74 U.S. (7 Wall.) 583, 602-04 (1868); Hess, 106 F.3d at 980-81, 41 USPQ2d at 1786-87 . As explained in Shatterproof Glass Corp. v. Libbey-Owens Ford Co., 785 F.2d 613, 624, 225 USPQ 634, 641 (Fed. Cir. 1985), "an inventor may use the services, ideas, and aid of others in the process of perfecting his invention without losing his right to a patent."

An assertion of incorrect inventorship must be based on facts proved by clear and convincing, corroborated evidence. Hess, 106 F.3d at 980, 41 USPQ2d at 1786 . The difficulty of determining legal inventorship has been recognized, see Jamesbury Corp. v. United States, 518 F.2d 1384, 1396, 183 USPQ 484, 489 (Ct. Cl. 1975) (inventorship is one of the most difficult issues in American patent law) and, to avoid inadvertent invalidity, 35 U.S.C. Section 256 permits correction of the designated inventorship of a patent when an error was made without deceptive intent:

Section 256 Whenever through error a person is named in an issued patent as the inventor, ***1233** or through error an inventor is not named in an issued patent and such error arose without any deceptive intention on his part, the Commissioner may, on application of all the parties and assignees, with proof of the facts and such other requirements as may be imposed, issue a certificate correcting such error.

See Stark v. Advanced Magnetics, Inc., 119 F.3d 1551, 1556, 43 USPQ2d 1321, 1325 (Fed. Cir. 1997) (error in inventorship may be corrected at any time if no deceptive intent).

The '154 patent as filed in the United States had named Dr. Lindgren as sole inventor. In the course of the reissue proceeding Dr. Lindgren filed a petition in the PTO to add Dan degrees Akerfeldt as a joint inventor. Lindgren and degrees Akerfeldt each filed declarations explaining their roles in the invention and declaring that the omission in naming degrees Akerfeldt was due to differences between United States and Swedish patent law, and was not done with intent to deceive.

M3 Systems challenged the joint inventorship of Lindgren and degrees Akerfeldt, and also stated that neither one was an inventor of the '056 patent's needles, but that Alan Taylor, President of Hart Enterprises, the company Radiplast retained to manufacture its new needles in the United States, was the sole inventor. Although Mr. Taylor did not appear at the trial, he stated in a deposition that he was not an inventor, but that he suggested the slot in the stylet flange to cooperate with a guide pin in the gun and prevent rotation of the needle. He said he sketched his design for Mr. Engstrom, although such a sketch was not produced. M3 states that Mr. Taylor gave written notice of his claim in 1990, before the reissue application was filed, but the record citations in M3's brief do not direct us to such notice.

It has long been the rule that one who asserts "inventor" status must provide clear and convincing evidence of supporting facts, including corroborating evidence. See Woodland Trust v. Flowertree Nursery, Inc., 148 F.3d 1368, 1371, 47 USPQ2d 1363, 1366 (Fed. Cir. 1998) (illustrating the historical distrust of uncorroborated oral testimony of prior invention and citing the "rule of reason" analysis of corroborating evidence in Price v. Symsyk, 988 F.2d 1187, 1194, 26 USPQ2d 1031, 1036 (Fed. Cir. 1993)). At the trial Mr. Engstrom disputed Mr. Taylor's statements, and the earliest depiction introduced of the flange with a slot was a Swedish document.

Alternatively, M3 Systems points to the design patents that were filed in the name of degrees Akerfeldt alone, as establishing that Dr. Lindgren was not a joint inventor of the needles with degrees Akerfeldt. Bard replies, and there is no dispute, that the design patents showed specific hub designs not shown in the utility patent. Whether degrees Akerfeldt was the sole inventor of specific hub designs does not negate his joint inventorship of the needles of the ' 056 patent, which are depicted and claimed broadly. Bard also stresses that if indeed there were error in inventorship, such errors are correctable and do not invalidate the patent absent deceptive intent. To invalidate a patent based on incorrect inventorship it must be shown not only that the inventorship was incorrect, but that correction is unavailable under section 256:

Section 256 [Para.2] The error of omitting inventors or naming persons who are not inventors shall not invalidate the patent in which such error occurred if it can be corrected as provided in this section. . . .

Although M3 contends that deceptive intent can be inferred from the omission of Taylor as an inventor, precedent requires that one who claims a share of inventorship must establish that right by clear and convincing evidence. Ethicon, 135 F.3d at 1465-66, 45 USPQ2d at 1552 ; Hess, 106 F.3d at 980, 41 USPQ2d at 1785-86 . Since such evidence was absent, the judgment of invalidity based on incorrect inventorship can not stand, and is reversed.

D. Violation of Reissue Requirements

The jury also found by special verdicts that the asserted '056 claims were invalid on the ground that the reissue requirements were not met. M3 Systems

explains in its brief that the jury found that "any purported error in the ' 154 patent could not be corrected by reissue," explaining that the errors were the error in inventorship and the error in failing to claim the needles in the original '154 patent.

[3] With respect to the argument that the correction of inventorship was improperly made by reissue, we have been directed to no legal or procedural error, for the prosecution history clearly shows that the error in inventorship was described in the reissue application and corrected by appropriate petition, filed and processed while the reissue application was pending. A petition to correct inventorship, 37 C.F.R. Section 1.324 (1991), may be filed during reissue proceedings. The error in inventorship was corrected before the reissue patent was granted, and thus the reissued patent names Lindgren and degrees Akerfeldt as the inventors. This procedure can not have provided ground for a reasonable jury's verdicts ***1234** of invalidity based on violation of reissue requirements.

[4] The other aspect that M3 Systems argued was not amenable to correction by reissue was the addition of claims to the needles per se. That argument incorrectly states the reissue law, for a primary purpose of the reissue statute is to enable the addition of claims to subject matter not claimed in the original patent. See Scripps Clinic & Res. Found'n v. Genentech, Inc., 927 F.2d 1565, 1575, 18 USPQ2d 1001, 1009 (Fed. Cir. 1991) (purpose of reissue statute is to avoid forfeiture of substantive rights due to erroneously claiming less than entitled, through error without intent to deceive); In re Wilder, 736 F.2d 1516, 1518-19, 222 USPQ 369, 371-72 (Fed. Cir. 1984) (purpose of reissue is to correct errors such as misunderstanding scope of the invention and claiming less than that to which the inventor was entitled).

M3 Systems states that since the needles were not claimed originally they were not "intended" to be claimed, and that absence of such intent is not an error correctable by reissue. That too is an incorrect statement of the law. An inventor's failure to appreciate the scope of an invention at the time of the original patent grant, and thus an initial intent not to claim the omitted subject matter, is a remediable error. See In re Amos, 953 F.2d 613, 619, 21 USPQ2d 1271, 1276 (Fed. Cir. 1991) (reissue application not subject to rejection for failure to demonstrate initial intent to claim, when subject matter of reissue claims satisfies Section 112 requirements); In re Weiler, 790 F.2d 1576, 1581, 229 USPQ 673, 676-77 (Fed. Cir. 1986) ("intent to claim" is shorthand for a means of measuring whether required error is present); In re Hounsfield, 699 F.2d 1320, 1322, 216 USPQ 1045, 1048 (Fed. Cir. 1983) (lack of "intent to claim" is only one factor to be considered).

M3 Systems also argues that the error in failing to claim the needles should have been corrected sooner. The reissue statute sets a two-year time limit for filing a broadening reissue application. This requirement was met. See 35 U.S.C. Section 251; In re Graff, 111 F.3d 874, 877, 42 USPQ2d 1471, 1473-74 (Fed. Cir. 1997) (broadened claims must be filed within two years); see also 37 C.F.R. Section 1.175 (1991). There is no requirement that a patentee act earlier rather than later during the two-year window established by statute.

M3 Systems has stated no basis in fact or law for its assertion that any reissue procedure was violated. The verdicts of invalidity on this ground are unsupported in law, and judgment based thereon is reversed.

E. The On-Sale Issue [FN4]

The jury also found that the asserted '056 claims were invalid on the ground that the new needle assembly had been "patented or published or in public use or on sale" in the United States more than one year before the filing date of the '154 patent application in the United States. See 35 U.S.C. Section 102(b), supra note 3. Since that filing date was July 30, 1986, the critical date for bar purposes is July 30, 1985.

Although the special verdicts did not distinguish among the statutory grounds of patented or published or in public use or on sale, the major focus at trial and on appeal is the issue of on sale. While M3 Systems also argued that there was a bar based on publication and public use, the only evidence referred to relates to the first generation gun and the Tru-Cut needles, which are acknowledged prior art and are not claimed in the patents in suit. M3's argument at trial that these prior art devices were also a bar to the '056 claims under section 102(b) is not pressed on appeal.

The '154 and '056 patents are directed to the second generation gun and new needles. Before the critical

date, indeed before the development of the second generation gun and new needles had been completed, Radiplast was engaged in a variety of activities directed to the United States market. These activities included demonstrating and promoting the first generation gun with the Tru-Cut needles, pursuing arrangements for clinical trials for the second generation gun and new needles through collaboration with a potential United States distributor, applying for FDA approval, arranging for manufacture of the needles in the United States, and related activities directed to commercial goals. Although Radiplast's final needle design was developed after the critical date, the issue at trial was the effect of these prior activities under the law of section 102(b).

Federal Circuit precedent on the on-sale bar requires consideration by the court of the totality of the circumstances in light of the various policies that underlie the bar. Precedent explains that "while a wide variety of factors may influence the on sale determination, ***1235** no single one controls the application of section 102(b), for the ultimate conclusion depends on the totality of the circumstances."Ferag AG v. Quipp, Inc., 45 F.3d 1562, 1566, 33 USPQ2d 1512, 1514 (Fed. Cir. 1995) ; see Envirotech Corp. v. Westech Eng'g Inc., 904 F.2d 1571, 1574, 15 USPQ2d 1230, 1232 (Fed. Cir. 1990).

Although a few cases have recognized the advantages of a bright line rule that would be applicable in all cases, that is, a defining event whereby an inventor will know when the bar will accrue, generally the court has undertaken to weigh the particular facts of the commercial activity against the particular policy considerations that apply to the situation, giving effect to the principle that "the policies or purposes underlying the on sale bar, in effect, define it."RCA Corp. v. Data General Corp., 887 F.2d 1056, 1062, 12 USPQ2d 1449, 1454 (Fed. Cir. 1989). Thus, in general, "this court has been careful to avoid erecting rigid standards for 102(b). "Western Marine Elecs., Inc. v. Furuno Elec. Co., 764 F.2d 840, 844, 226 USPQ 334, 337 (Fed. Cir. 1985); see Petrolite Corp. v. Baker Hughes, Inc., 96 F.3d 1423, 1425, 40 USPQ2d 1201, 1203 (Fed. Cir. 1996) ("This court has emphasized that the totality of the circumstances must be considered in determining whether a particular event creates an on-sale or public use bar." (quoting U.S. Environmental Prods., Inc. v. Westall, 911 F.2d 713, 716, 15 USPQ2d 1898, 1901 (Fed. Cir. 1990))).

The determination of whether a product was on sale in terms of section 102(b) is a question of law. See Micro Chem., Inc. v. Great Plains Chem. Co., 103 F.3d 1538, 1544, 41 USPQ2d 1238, 1243-44 (Fed. Cir. 1997) (discussing precedent and applying the totality of the circumstances standard as a matter of law);1444, 14451, 27 USPQ2d 1297, 1303 (Fed. Cir. 1993)KeyStone Retaining Wall Sys., Inc. v. Westrock, Inc., 997 F.2d (explaining relevant factual inquiries); Baker Oil Tools, Inc. v. Geo Vann, Inc., 828 F.2d 1558, 1562-64, 4 USPQ2d 1210, 1213-14 (Fed. Cir. 1987) (discussing various factors to be weighed in context of experimental testing by third persons).

The various policy considerations include the policy of providing a limited but normally sufficient time (one-year) for the inventor to test the commercial reception of the invention before deciding whether it warrants patenting; the policy of limiting the period during which the patentee may delay entering into the patent system for the purpose of deferring the end of the period of patent- based exclusivity; the policy favoring prompt public disclosure of inventions through the patent system; and the policy of recognizing the practical consideration whereby the value of an invention may not be known until it is publicly tested. Depending on the dominant policy considerations in the particular case, applied to the factual circumstances of that case, the Federal Circuit has reached a variety of conclusions as to when the on-sale bar arose. The court's precedent illustrates rulings ranging from the requirement that the patented product was produced and available commercially before the on-sale bar started to accrue, to rulings that the bar was triggered before the invention had been completed.

Before the critical date for the '056 patent, July 30, 1985, three sets of events were explored at trial. The facts are not in dispute; the question is whether, as a matter of law, the on-sale bar arose in these circumstances:

1. The Clinical Trials

The clinical trials were arranged by American Pharmaseal, Radiplast's potential distributor in the United States, and were conducted in August and September 1985 (after the critical date) using the second generation guns and new needles. In January 1985 Thomas Engstrom of Radiplast had quoted to

Pharmaseal the price for 12 guns and 500 needles for use in the trials. Pharmaseal later that spring requested 10 guns and 250 needles, for which Radiplast sent an invoice in June 1985. Mr. Engstrom testified that this payment was to defray some of Radiplast's costs in providing these devices, and was so understood. It was not disputed that the transaction produced no profit for Radiplast.

M3 Systems asserts that Radiplast sold the 10 guns and 250 needles to Pharmaseal, pointing out that a standard sales invoice was used. Bard replies that this was a transaction between collaborators, not a commercial sale and not a sale for commercial distribution. Dr. Lindgren testified that he visited the four United States hospitals that were testing the device (after the critical date), to explain its use and to see how it worked in different tissues, operated by different doctors. Bard stresses that the devices were not sold, that all but one were returned by the hospitals after the clinical trials, and unused needles were destroyed.

Generally cost defrayal arrangements between collaborators are not deemed to be invalidating sales, nor are payments for use substantially for test purposes. See In re Mahurkar, 71 F.3d 1573, 1577, 37 USPQ2d 1138, 1142 (Fed. Cir. 1995) (actual sale of two prototype catheters "did not place the ***1236** invention in the public domain or lead the public to believe that the device was freely available"); Ethicon, Inc. v. United States Surgical Corp., 762 F. Supp. 480, 506-07, 19 USPQ2d 1721, 1740 (D. Conn. 1991) (clinical tests by surgeon not a public use under Section 102(b)), aff'd, 765 F.2d 1062 (Fed. Cir. 1992) (Table); Baker Oil Tools, 828 F.2d at 1564, 4 USPQ2d at 1214 (discussing factors in deciding whether the purpose of testing was primarily experimental). In its submissions to the PTO during the reissue proceeding Radiplast characterized the transaction concerning the 10 guns and 250 needles as for experimental purposes.

It is not disputed that the sole purpose of this transaction was to make the devices available to the four selected hospitals for a limited test period. Radiplast's arrangement with Pharmaseal for payment or defrayal of the cost of providing the devices was not a sale or offer of sale as contemplated by section 102(b). It contravenes none of the policies underlying the on sale bar for Radiplast to have recouped these costs. Upon considering the totality of the circumstances, I conclude that an on-sale bar did not arise based on this transaction between Radiplast and Pharmaseal in connection with the clinical trials.

2. The Bulk Price Quotation

In January 1985 Radiplast quoted to Pharmaseal prices for various bulk quantities of up to 50,000 needles. At that time the new needles were still being modified, and the record shows that design changes were made well after January 1985. Mr. Engstrom of Radiplast testified that the quotation was information for a potential distributor, in the event that Pharmaseal accepted that role (it did not). The bulk price quotations were in a telex that stated, "This is to give you an indication of the price levels. We have to meet and discuss more in detail all things related with the marketing of our biopsy instrument in US." It was not disputed that the quotation was for modified needles, and that both parties understood that the modified needles were not yet available.

M3 Systems argues that since the first generation device had been shown to operate for its intended purpose using Tru-Cut needles, the inventor had already convinced himself that he had a satisfactory product that he wished to commercialize in the United States, and thus that the bulk price quotation, even if for needles not yet developed, was an on-sale event. M3 stresses that the price quoted for bulk quantities included a profit for Radiplast, unlike the price for the clinical trial quantities.

Quotation of a sales price to a potential distributor of a product that is not available for sale and distribution does not of itself establish an on-sale bar. See Continental Can, 948 F.2d at 1270, 20 USPQ2d at 1750 (price terms set between collaborators in joint research not an on-sale bar); Shatterproof Glass, 758 F.2d at 622, 225 USPQ at 639 ("clear weight of authority is that a bare offer to sell does not ipso facto satisfy the 'on sale' bar"). A primary policy served by the on-sale bar is to provide time for an inventor to determine the reception of his invention in the marketplace before entering into the patent system, while the one-year limit prevents undue lengthening of the period of exclusivity. The policy is served when cognizance is taken of whether the invention is ready for commercial use at the time that customer contacts are made. Although exceptions have arisen on particular facts, normally the on-sale bar does not accrue based on customer contacts made while the product is still being developed or tested. See KeyStone, 997 F.2d at 1451, 27 USPQ2d at 1303 (on-

sale bar "requires that the device asserted to be on sale was operable"); Seal-Flex Inc. v. Athletic Track & Court Constr., 98 F.3d 1318, 1322, 40 USPQ2d 1450, 1452 (Fed. Cir. 1996) (invention not completed if it required testing under conditions of actual use).

In this case, the circumstances of the incomplete stage of development of the second generation gun and proposed new needles at the time of this price quotation, the potential but not established distributor relationship underlying this quotation, the planned clinical collaboration, and the non- existence of a completed final product, negate the accrual of an on-sale bar from this price quotation. It seems clear that neither Radiplast nor Pharmaseal expected that this bulk price quotation would be followed by the placement of an order. To satisfy the on-sale requirement of section 102(b) there must be more than an informational exchange of price information, when there is no reasonable contemplation that the quotation will be followed by purchase and sale as a commercial transaction.

I conclude that the verdicts of invalidity based on the on-sale bar can not be supported by this bulk price quotation.

3. The Correspondence with Dr. Phelps

The third event raised by M3 Systems occurred in November 1984. Mr. Engstrom of Radiplast responded to a letter written in September 1984 by Dr. Phelps, a physician ***1237** in Alabama, who had seen a demonstration and brochure for the first generation device and wrote to Sweden for information. Engstrom wrote back that he hoped to start marketing a second generation device and new needles in the United States in early 1985, and that if Dr. Phelps did not wish to wait until United States distribution was arranged he could order directly from Sweden; the letter quoted prices for a gun and needles. No further correspondence ensued. Dr. Phelps testified that he expected that had he sent an order it would have been filled, and that he knew nothing about the difference between "generations." Mr. Engstrom testified that neither the new needles nor the completed second generation gun was available when he answered Dr. Phelps.

An offer of sale originating in a foreign country, directed to a consumer in the United States, can establish an on-sale bar as to what was offered. In re Caveney, 761 F.2d 671, 676-77, 226 USPQ 1, 4 (Fed. Cir. 1985). The demonstration and brochure that led to Dr. Phelps' inquiry were of the first generation device, which used Tru-Cut needles. Although the details of Radiplast's product changes were not explained to Dr. Phelps it was undisputed that an order, if placed, could not have been filled at that time with the second generation gun and needles. Cf. King Instrument Corp. v. Otari Corp., 767 F.2d 853, 860, 226 USPQ 402, 407 (Fed. Cir. 1985) (finding it significant that purchaser could discern that it was the later-patented invention being offered for sale).

At the time of Mr. Engstrom's letter the second generation device and needles were in an early development stage. Although Dr. Phelps was not told the details of these developments, this correspondence did not raise an on-sale bar to a product not yet developed. As held in Robotic Vision Sys., Inc. v. View Eng'g, Inc., 112 F.3d 1163, 1167-68, 42 USPQ2d 1619, 1623 (Fed. Cir. 1997), "subsequent completion of an invention after the critical date does not relate back to the date of an earlier alleged offer of sale."See also Micro Chem., 103 F.3d at 1544-45, 41 USPQ2d at 1243 (no on-sale bar when invention not completed at time of offer, only prototype and sketch of proposed configuration); Shatterproof Glass, 758 F.2d at 622, 225 USPQ at 639 (not an on-sale bar to solicit orders before invention completed); cf. Pfaff v. Wells Elecs., Inc., 124 F.3d 1429, 43 USPQ2d 1928 (Fed. Cir. 1997), cert. granted, 118 S. Ct. 1183 (1998) (No. 97-1130) (although invention not reduced to practice because no physical embodiment had been made, the firm purchase order and delivery date accrued the on-sale bar) (citing UMC Elecs. Co. v. United States, 816 F.2d 647, 2 USPQ2d 1465 (Fed. Cir. 1987)). On the totality of the circumstances, considering the relevant policies and the undisputed facts, I conclude that this letter to Dr. Phelps, written in response to an inquiry about the first generation device, which resulted from a brochure on the first generation device, stating the price for the second generation device and needles before they were fully developed and before they were available, did not trigger the on-sale bar.

Upon de novo review of the totality of the circumstances, with due consideration to the applicable policies, the undisputed facts, and drawing factual inferences in favor of the verdicts, I conclude that the verdicts of invalidity based on a section 102(b) bar are incorrect; I would reverse the judgment on that ground. [FN5]

II

INFRINGEMENT OF THE '056 PATENT

In view of the majority's affirmance of the judgment of invalidity, we do not reach the issue of infringement of the '056 patent. That judgment is vacated.

III

VALIDITY OF THE '308 PATENT

The '308 patent is directed to the third generation gun. The jury found the asserted claims of the '308 patent not infringed, and invalid or unenforceable on the grounds of anticipation, obviousness, and insufficient ***1238** supporting description, as well as for fraud, misuse, and violation of antitrust law, as discussed in Parts V-VII, post.

Claims 15 and 16 were at issue, with emphasis added to show the claim terms whose construction is relevant to the issues of patent validity or infringement: 15. A tissue sampling device comprising:

a guide sleeve having front and rear guide sleeve ends and defining a longitudinal axis extending between said front and rear guide sleeve ends, said front guide sleeve end having an opening therethrough;

a hollow first needle positioned within said guide sleeve and extendable from said opening, said hollow first needle being moveable along said axis;

a second needle extending through said hollow first needle and moveable along said axis, said second needle having a tip which is extendable from said hollow first needle and said opening, and said second needle further including a tissue sample receiving recess;

a first needle head coupled to said hollow first needle and mounted within said guide sleeve for movement along said axis to move said hollow first needle along said axis;

a second needle head coupled to said second needle and mounted within said guide sleeve for movement along said axis to move said second needle along said axis;

a first spring disposed within said guide sleeve and operatively associated with said second needle head, said first spring being capable of being placed into an energized mode to store energy, and said first spring being releasable from said energized mode to propel said second needle head along said axis towards said opening, such that said tip of said second needle is extended from said hollow first needle, whereby a tissue sample can be captured within said recess;

a second spring positioned within said guide sleeve and operatively associated with said first needle head, said second spring being capable of being placed into an energized mode to store energy, and said second spring being releasable from said energized mode to propel said first needle head along said axis towards said opening, said hollow first needle being extended from said opening such that said recess of said second needle is enclosed by said hollow first needle;

a first latch means selectively releasable from outside said guide sleeve for releasably holding said first spring in said energized mode;

a second latch means for releasably holding said second spring in said energized mode, said second latch means being releasable in response to and subsequent to release of said first spring; and sequential energizing means operative to move said first needle head along said axis towards said rear guide sleeve end to cause said second latch means to hold said second spring in said energized mode, and subsequently to move said second needle head along said axis towards said rear guide sleeve end to cause said first latch means to hold said first spring in said energized mode.

Claim 16 is the same as claim 15 except for the last clause, which includes the selective retraction of the stylet to expose the tissue sample:

16. . . . energizing means operative to move said first needle head and said second needle head along said axis towards said rear guide sleeve end to cause said first latch means to hold said first spring in said energized mode and to cause said second latch means to hold said second spring in said energized mode, said energizing means being selectively operative to move said first needle head but not said second needle head towards said rear guide sleeve end, whereby said hollow first needle is selectively retractable to expose said tissue sample receiving means in said second

needle.

A. Support by the Written Description

The jury found claims 15 and 16 "not supported by the description contained in the specification." M3 Systems explains that the issue was the meaning of the claim terms "sequential energizing" and "energizing means." The district court had permitted the jury to resolve this disputed issue of claim construction. On this appeal we give de novo review to the issues relevant to the construction and interpretation of the claims. See Cybor, 138 F.3d at 1454-56, 46 USPQ2d at 1172-75 .

M3 Systems states that "sequential" should be construed, and was construed by the jury, to permit no overlap of needle movement during the energizing step. M3 states that since the patent shows that the second needle can start to move before the first needle has completed its movement, the written description does not support the claims. M3 states, as it did at trial, that since the specification does not describe how to obtain elimination of all overlap of needle ***1239** movement, the claims are not supported by the written description and are invalid.

> [5] Bard agrees that the specification shows a slight overlap in the movement of the needles, whereby the second needle starts to move just before the first needle has completed its movement and the first spring latches. Thus, Bard contends, correct interpretation of the claims allows for this slight overlap in needle movement. Bard states that it is incorrect to construe the claims contrary to the specification, and then to hold the claims invalid because they are contrary to the specification. Bard is of course correct; the claims are construed in accordance with the rest of the specification of which they are a part, and not contrary to it. See Slimfold Mfg., 810 F.2d at 1116, 1 USPQ2d at 1566 ; SRI Int'l v. Matsushita Elec. Corp. of Am., 775 F.2d 1107, 1125, 227 USPQ 577, 585 (Fed. Cir. 1985) (in banc).

The specification illustrates the sequential energizing of the needles as having some overlap in movement of the needles. The term "sequential" in the claims is in accordance with this description in the specification; no usage or exemplification of the sequential movement requires eliminating all overlap. It is incorrect to construe the claims as barring all overlap, as urged by M3 Systems. On the correct claim construction, no reasonable jury could have found that the claims are not supported by the description in the specification. It is thus apparent that the jury either adopted M3's erroneous claim construction, or incorrectly applied the law governing claim construction to the undisputed facts of the structure described in the specification.

On the correct claim construction the written description is in accordance with and in support of the claims. The judgment of invalidity on this ground is reversed.

B. Anticipation

The jury also found claims 15 and 16 invalid based on anticipation. "Anticipation" requires that the identical invention was already known to others, that is, that the claimed invention is not new. See Minnesota Mining & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc., 976 F.2d 1559, 1572, 24 USPQ2d 1321, 1332 (Fed. Cir. 1992) ("In order to anticipate, the [reference] must sufficiently describe the claimed invention to have placed the public in possession of it.") M3 Systems argued that anticipation arose on the published PCT application describing the first generation biopsy gun, and on the device itself. It was not disputed, however, that the first generation gun lacks the integrated mechanical energizing structure described and claimed in the '308 patent, and that the PCT application does not show such structure.

M3 Systems' argument was that when the claims are correctly construed they are anticipated. M3 states that on the claim construction reached by the jury in finding claims 15 and 16 unsupported by the written description, whereby the term "sequential" is defined as barring all overlap in needle movement, the structure in the specification is inconsistent with the claims and therefore must be disregarded. M3 argues, as we understand it, that since "energizing means" and "sequential energizing means" are in means-plus-function form, it is appropriate to disregard the structure in the specification that is inconsistent with the claim language, leaving the claimed functions with "no disclosed supporting structure," quoting from M3's brief. Thus, according to M3, these claim terms are directed only to function, and can be anticipated by any prior art that shows the function of energizing or sequential energizing, without limit to how that function is performed. Thus M3 argues that since the PCT application and the first generation gun are

manually sequentially energized, one spring at a time, the jury correctly found anticipation by the first generation gun and the PCT application.

Indeed, the jury verdicts can be understood only if one adopts so tortured a view of the law. As we have discussed, it is incorrect to construe claims contrary to the specification, and it is incorrect to construe terms in means- plus-function form as disembodied from the structure in the specification. M3 Systems' witnesses readily admitted that the integrated mechanized gun described and claimed in the '308 patent is different from the first generation gun and the description of that gun in the PCT application. On the undisputed facts and the correct law, a reasonable jury could not have found the '308 claims anticipated thereby. The judgment of invalidity for anticipation must be reversed.

C. Obviousness

M3 Systems argues that the third generation gun of the '308 patent would have been obvious in view of the PCT application and the first generation gun, in combination with the '154 patent describing the second generation gun. M3 states that the third generation is an obvious combination of elements found in the first and second generations. See discussion, Part I.B. ante, of the law of obviousness. There was no dispute as to the scope and content of this prior art, or as to the ***1240** elements in the third generation gun that were not in either the first or second generations. The only dispute was the ultimate question of whether the third generation gun would have been obvious from what had gone before.

M3 Systems contends that for the third generation the inventor simply changed the integrated mechanical cocking mechanism of the second generation gun to accomplish mechanically the sequential cocking that was necessarily done when the first generation gun was manually cocked, one spring at a time. Bard replies that the one-at-a-time cocking of the springs in the first generation, by hand or by miniature crowbar, does not teach or suggest the integrated automatic sequential cocking of the third generation, and that there is no teaching or suggestion in the prior art to make such a combination, or of the structure having the improved ease of handling of the third generation gun. Bard also points to the other new structural features of the third generation whereby the needles can be retracted separately after tissue sampling.

The ultimate question is whether, from the evidence of the prior art and the knowledge generally available to one of ordinary skill in the relevant art, there was in the prior art an appropriate teaching, suggestion, or motivation to combine components in the way that was done by the inventor. See, e.g., Uniroyal, 837 F.2d at 1050, 5 USPQ2d at 1438 ; ACS Hosp. Sys., Inc. v. Montefiore Hosp., 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed. Cir. 1984). The ultimate determination of obviousness is a legal conclusion. When this legal conclusion is drawn by the jury the verdict is reviewed, as discussed in Part I.B, to determine whether substantial evidence supports the factual findings necessary to support the legal conclusion, with due consideration to the presumption of validity and the standard of proof.

[6] Bard points out that its rotating sleeve mechanism for sequential energizing is a marked distinction from its earlier devices, even were the concept of sequential energizing deemed to be derivable from the manual operation of the first generation. M3 Systems does not cite any reference suggesting the structure employed in the third generation gun, or any suggestion of mechanical sequential energizing, or indeed the other features of the third generation. Those contributions came from the inventor, not the prior art. See Uniroyal, 837 F.2d at 1050, 5 USPQ2d at 1438 . We have been directed to no teaching or suggestion of this combination in the descriptions of the first and second generation guns, viewed separately or together. Thus the verdicts of invalidity on the ground of obviousness are without essential factual support, and can not stand.

IV

INFRINGEMENT OF THE '308 PATENT

The jury found that M3 Systems did not infringe claims 15 and 16 of the ' 308 patent. Because the special verdicts discussed in Part III.A (that there is not support for these claims in the written description) require an incorrect claim construction, we have reviewed the verdicts of noninfringement on the correct construction, i.e., that claims 15 and 16 do not require a total absence of overlap in the sequential movement of the needles during energizing. Bard contends that on the correct claim construction the verdicts of noninfringement can not stand. Bard is entitled to a new trial if a jury reasonably could have reached verdicts of infringement upon correct claim

construction and correct application of the law of infringement. However, if only one result is supportable in law and on undisputed facts, judgment as a matter of law is appropriate. See Strattec, 126 F.3d at 1419, 44 USPQ2d at 1036 .

On appeal Bard argues only the issue of sequential energizing, asserting literal infringement under section 112 paragraph 6. M3 Systems does not dispute, and indeed emphasizes, that in its ProMag devices there is sequential energizing with a slight overlap in needle movement. However, M3's performance of the function of sequential energizing was not the only disputed issue with respect to infringement. M3 also points out that its device is a box-type biopsy gun and does not contain a "guide sleeve" as required by the claims, and that the M3 ProMag guns use linear tensioning whereas the '308 device performs counter-rotational tensioning, such that the structure used by M3 is not equivalent to that shown in the '308 specification, applying section 112 paragraph 6 to the energizing means of the '308 claims.

M3 Systems states that the '308 patent draws a distinction between box- type biopsy guns such as those made by M3 wherein the housing is merely a container for the device, and guns embodying a mechanism wherein the guide sleeve and a tensioning sleeve interact and serve as part of the cocking mechanism. M3 argued at trial that its housing is independent, whereas in the ' 308 specification the gun is housed in a two-part structure ***1241** wherein the inner part is the guide sleeve and the outer part is the tensioning sleeve and rotates about the inner part. These sleeves bear cam surfaces and slots that interact with the flanges on the needle heads and thus serve as part of the cocking mechanism. M3 states that its gun has neither a guide sleeve nor a tensioning sleeve, and that its housing is merely the container for the device, and is unconnected with the cocking mechanism.

Although the claims in suit do not require a tensioning sleeve, see D.M.I., Inc. v. Deere & Co., 755 F.2d 1570, 1574, 225 USPQ 236, 239 (Fed. Cir. 1985) (improper to import limitation from one claim into another claim lacking the limitation), the guide sleeve is described in the specification as "the inner sleeve or guide sleeve." The specification shows and the claims require that the guide sleeve perform a guiding function for the cocking mechanism. Bard does not assert that such a structure is found in the M3 guns. Nor does Bard raise on this appeal any issue of equivalency under the doctrine of equivalents.

At the trial the parties presented evidence on how the patented and accused devices worked, and the court instructed the jury as to the applicable law of infringement of means-plus-function claims. For the energizing means Bard was required to establish, by a preponderance of evidence, that M3 Systems' device embodies the structure described in the '308 specification or an equivalent thereof. 35 U.S.C. Section 112 Para.6; Valmont Indus., Inc. v. Reinke Mfg. Co., 983 F.2d 1039, 1041-42, 25 USPQ2d 1451, 1453-54 (Fed. Cir. 1993); Texas Instruments, Inc. v. United States Int'l Trade Comm'n, 805 F.2d 1558, 1562-63, 231 USPQ 833, 834-35 (Fed. Cir. 1986). Since the structure of the M3 energizing means is not the same as that described in the '308 specification, the issue was whether the structures are equivalent. See D.M.I., 755 F.2d at 1575, 225 USPQ at 239 (" [T]he sole question is whether the single means in the accused device which performs the function stated in the claim is the same as or an equivalent of the corresponding structure described in the patentee's specification as performing that function.") The determination of infringement under section 112 paragraph 6 is a factual question. In re Hayes Microcomputer Prods. Inc. Patent Litig., 982 F.2d 1527, 1541, 25 USPQ2d 1241, 1251 (Fed. Cir. 1992); Intel Corp. v. United States Int'l Trade Comm'n, 946 F.2d 821, 841, 20 USPQ2d 1161, 1178 (Fed. Cir. 1991); D.M.I., supra%i.

There was no dispute that the function of sequential energizing is performed in the M3 Systems' guns; the only question was whether the M3 guns employ the same or an equivalent of the structure described in the '308 specification. The accused equivalent structure need not have been known at the time the patented invention was made. See Texas Instruments, 805 F.2d at 1563-64, 231 USPQ at 834-35 ("It is not required that those skilled in the art knew, at the time the patent application was filed, of the asserted equivalent means of performing the claimed functions. . . .")

It was explained at trial that to achieve sequential energizing in the '308 device the outer tensioning sleeve is rotated about the inner guide sleeve; cam surfaces on the interior of the tensioning sleeve push against wings built directly into the needle heads to compress the two springs in sequence, pressing them rearward into the locked position. In contrast, in the M3 Systems device a handle connected through the rear of the housing acts on sleds bearing the needles;

M3's device relies on the lever-action of the handle, as opposed to a rotating sleeve, to pull, rather than push, the needle sleds sequentially back toward their respective latches. Bard had argued at trial, in connection with the issue of validity, that the claims "must be interpreted as means-plus- function terms in accordance with Valmont," and cited its "external integrated energizing mechanism that converts rotary motion to linear motion" to distinguish the '308 gun from its own earlier device. Claims must be interpreted the same way for determining infringement as was done to sustain their validity.

> [7] A reasonable jury could have found that the structure using rotational tensioning as the energizing means is substantially different from the energizing structure in the M3 Systems guns. Although Bard argues that it suffices for infringement if the energizing is achieved with the slight overlap shown in the '308 patent, that is, if the function of sequential energizing is performed, claims written in the form authorized by section 112 paragraph 6 are limited by the structure described and equivalents of that structure. Performance of the same function does not of itself establish infringement.

Bard directs us to the doctrine of claim differentiation, and argues that it is incorrect to interpret the "sequential energizing means" of claim 15 as limited to the structure in the specification, because other claims, not at issue, specifically state that structure. Bard argues that its claims in suit are broader in that they state only the function of sequential energizing, and that they therefore warrant broader scope than the ***1242** claims that state a specific energizing structure. However, as we have discussed, claims that are written in the form authorized by section 112 paragraph 6 are by statute limited to the structure described in the specification and equivalents of that structure. As discussed in Laitram Corp. v. Rexnord, Inc., 939 F.2d 1533, 1538, 19 USPQ2d 1367, 1371 (Fed. Cir. 1991) a "means-plus-function limitation is not made open-ended by the presence of another claim specifically claiming the disclosed structure which underlies the means clause or an equivalent of that structure."

Applying this law, and based on the absence of a guide sleeve or any counterpart structure, and the differences in the structures of the energizing mechanisms, we conclude that on the correct claim interpretation a reasonable jury could find that claims 15 and 16 are not infringed. The judgment of noninfringement of the '308 patent is affirmed.

V

FRAUD

M3 Systems charged that Bard had committed both fraud and inequitable conduct in prosecuting the '056 and '308 patents. The jury was not asked to decide the issue of inequitable conduct, which was reserved to the judge and withdrawn by M3 after the favorable verdicts on the question of fraud. The jury found that it had been established by clear and convincing evidence that each of the '056 and the '308 patents had been procured by fraud in the Patent and Trademark Office.

Fraud in the procurement of a patent requires proof of the elements of fraud as developed in the common law: (1) that a false representation of a material fact was made, (2) with the intent to deceive, (3) which induced the deceived party to act in justifiable reliance on the misrepresentation, and (4) which caused injury that would not otherwise have occurred. See Nobelpharma AB v. Implant Innovations, Inc., 141 F.3d 1059, 1069-70, 46 USPQ2d 1097, 1105-06 (Fed. Cir. 1998); Norton v. Curtiss, 433 F.2d 779, 792-94 & n.12, 167 USPQ 532, 543-45 & n.12 (CCPA 1970) (citing W. Prosser, Law of Torts Sections 100- 05 (3d ed. 1964)).

The tort of fraud requires that there was a successful deception, and action taken by the person deceived that would not have otherwise been taken. Applied to patent prosecution, fraud requires (1) a false representation or deliberate omission of a fact material to patentability, (2) made with the intent to deceive the patent examiner, (3) on which the examiner justifiably relied in granting the patent, and (4) but for which misrepresentation or deliberate omission the patent would not have been granted. A finding of fraud can of itself render the patent unenforceable, and when accompanied by the elements of violation of the Sherman Act, as discussed in Part VI, can incur additional consequences.

To establish fraud for purposes of antitrust violation the defendant "must make a greater showing of scienter and materiality" than when seeking unenforceability based on conduct before the Patent Office. 6 Donald S. Chisum, Chisum on Patents

Section 19.03[6] [e] (rel. 47 1993) (citations omitted). In Walker Process Equip., Inc. v. Food Mach. & Chem. Corp., 382 U.S. 172, 177, 147 USPQ 404, 407 (1965) the Court clarified that "knowing and willful" fraud must be shown, and is predicate to potential antitrust violation. As explained in Handgards, Inc. v. Ethicon, Inc., 601 F.2d 986, 996, 202 USPQ 342, 351 (9th Cir. 1979), " [t]he road to the Patent Office is so tortuous and patent litigation is usually so complex, that 'knowing and willful fraud' as the term is used in Walker can mean no less than clear, convincing proof of intentional fraud involving affirmative dishonesty, 'a deliberately planned and carefully executed scheme to defraud * * * the Patent Office.' . . . Patent fraud cases prior to Walker required a rigorous standard of deceit . . . . Walker requires no less." (Emphasis and elisions in original.) The requirements of common law fraud are in contrast with the broader sweep of "inequitable conduct," an equitable defense that may be satisfied when material information is withheld with the intent to deceive the examiner, whether or not the examiner is shown to have relied thereon. See Kingsdown Med. Consultants v. Hollister, Inc., 863 F.2d 867, 872, 9 USPQ2d 1384, 1389 (Fed. Cir. 1988).

M3 Systems stated that Bard made myriad material misrepresentations in prosecuting the '056 and the '308 patents, including the following: the incorrect inventors were named; actual samples of the Tru-Cut needles and the first generation device were not provided to the examiner; the Baxter patent on the Tru-Cut needle and two Lindgren articles on the first generation device were not provided to the examiner; the material submitted to the FDA was not provided to the examiner; the examiner was not told of the co-pending design patents; and the examiner was not provided with all of the evidence on the on- sale issue. Bard responded that ***1243** there is no substance to any of these assertions; that all material information was presented to the examiner; that there was no intent to deceive the examiner; that the examiner was not deceived; and that the evidence points to good faith in the prosecution of these patents. Good faith is an absolute defense to the charge of common law fraud. See Walker Process, 382 U.S. at 177, 147 USPQ at 407 .

[8] M3 Systems argues that any omission in the submissions to the PTO is "necessarily material, because the allowance of the application is the intended natural consequence of that submission." That is not a correct statement of the law. There is no presumption that information not filed by an applicant was material simply because patentability ensued. To establish culpability any omission must be of a fact material to patentability and it must be a deliberate misrepresentation, whether by omission or misstatement, that was intended to and did mislead the examiner into taking favorable action that would not otherwise have been taken. Intent to mislead or to deceive must be proved by clear and convincing evidence. See Walker Process, supra. Deceptive intent is not inferred simply because information was in existence that was not presented to the examiner; and indeed, it is notable that in the usual course of patent prosecution many choices are made, recognizing the complexity of inventions, the virtually unlimited sources of information, and the burdens of patent examination. See Northern Telecom, 908 F.2d at 939, 15 USPQ2d at 1327 (discussing the ease with which routine patent prosecution may be portrayed as tainted conduct).

Following are the actions that M3 Systems presented as probative of fraud in the prosecution of the '056 or the '308 patent:

1. The Inventorship Issue

This issue was discussed ante in connection with the validity of the ' 056 patent. There was no evidence of intent to deceive in correcting the inventorship to include Mr. degrees Akerfeldt with Dr. Lindgren as joint inventors. The question of Mr. Taylor's role as a possible inventor did not present substantial evidence of fraud. Indeed, since the inventorship issue was not grounds of invalidity, it can not satisfy the "but for" test of fraud.

2. Provision of Actual Models to the Examiner

M3 Systems argued that Bard should have provided the reissue examiner with actual models of the first generation gun and the Tru-Cut needles, in addition to the PCT application and publications describing the needles. The PCT application described the first generation gun, and descriptions of the Tru-Cut needles were before the examiner. Reviewing the prosecution history we do not discern substantial evidence of material withholding, for cumulative information is not material to patentability, and there was no evidence of deceptive intent or that the examiner was deceived into granting the reissue. This issue can not support the verdict of fraud.

3. Provision of On-Sale Information to the Examiner

Bard filed with the PTO descriptions of the transactions involving Radiplast and Pharmaseal before the critical date, accompanied by documents including the invoice for the 10 guns and 250 needles for the clinical trials, the bulk price quotation discussed ante in connection with the on-sale issue, and declarations concerning the hospital tests and the proposed distribution relationship between Radiplast and Pharmaseal. M3 Systems states that Bard should have also disclosed to the PTO Radiplast's sales activities for the first generation device, Radiplast's letters to doctors concerning the clinical trials, the fact that the bulk price quotation included a profit, and Radiplast's letter to Dr. Phelps.

Concerning Dr. Phelps, Bard answers that it submitted to the PTO all the relevant material it had obtained. The letter to Dr. Phelps was obtained after suit was filed, during discovery of Radiplast's files in Sweden. There was no evidence that Bard had obtained and withheld this information during the reissue prosecution. With respect to the bulk price quotation, M3 Systems states that Bard should have flagged this document and described its significance to the examiner, lest it be overlooked in the volume of paper. Bard responds that the documents provided to the examiner were a record of Radiplast's efforts to find a distributor and its transactions with Pharmaseal, and that the total number of documents was not so voluminous, or the contents so difficult to understand, as to support an inference of intentional concealment of any particular document that was filed. We agree that these documents, all in the prosecution history, are easily read. [FN6]

***1244** On reviewing these filings in the PTO we have been directed to no evidence of material withholding or the provision of false information, or of intent to deceive or actual deception. The additional subject matter that M3 states should have been included was not shown to be material or other than cumulative. These actions did not constitute substantial evidence of fraud.

4. Disclosure of the Information Filed with the FDA

None of the material provided us with respect to Radiplast's 510(k) pre- market notification filed with the Food & Drug Administration supports a finding of fraud in the patent prosecution. M3 Systems concentrates on the presence in this package of needle drawings made by Hart Enterprises, the designated manufacturer. As we have explained, the inventorship issues that have been raised do not provide substantial evidence of fraudulent procurement of these patents.

5. Disclosure of the PCT Application

The PCT application had been submitted to the PTO during prosecution of the '154 patent and again during the '056 reissue proceedings. M3 Systems states that Bard withheld the PCT application from the examiner of the '308 patent and then mischaracterized it.

M3 Systems stated at trial and repeats on this appeal that Bard submitted the PCT application to the examiner of the '308 patent only after allowance of the '308 claims in suit, and then falsely represented that it was relevant solely to newly added claims 21-23 (as then numbered). Bard complains that M3 misstated at trial, and continues to misstate, these facts. We must agree. The '308 prosecution history in the record shows that Bard cited the PCT application and filed a copy thereof with a Supplemental Information Disclosure Statement accompanying Bard's first response, filed October 13, 1989, to the first Office Action. Contrary to M3's statements, the prosecution record shows that no claims had been allowed or held allowable when the PCT application was submitted to the PTO.

In submitting the PCT Application Bard's patent attorney pointed out the aspect of that application that M3 Systems has stated is of greatest significance, viz., the separate and thus sequential hand cocking of the springs in the first generation device. In the Remarks section of the response Bard discussed claims 21-23, the claims specific to sequential energizing. We discern no support for M3's argument that Bard misrepresented the content of the PCT application, or that the examiner did not consider the PCT application adequately. The examiner initialed on December 15, 1989 that he had considered this reference, the same day a telephone interview was held that led to an examiner's amendment, followed by allowance on January 3, 1990. The charge of fraud based on these events is totally without substance.

Conclusion

These asserted flaws in patent prosecution, separately or taken together, do not constitute substantial evidence of fraud. The verdicts of fraud in

procuring the '056 and '308 patents can not stand, and the judgment on these verdicts is reversed.

VI

ANTITRUST ISSUES

Antitrust violation was found on special verdicts that Bard by anticompetitive conduct had monopolized or attempted to monopolize the relevant markets for each of fully automated biopsy guns and needles, guns alone, and replacement needles. The jury instructions on the antitrust count identified three separate claims; first, that the patents were procured by fraud followed by attempts to enforce the fraudulently procured patents; second, that Bard threatened and then brought suit knowing that its patents were invalid, unenforceable, or not infringed; and third, that Bard unlawfully leveraged its monopoly power in the guns to obtain a competitive advantage in replacement needles by modifying its gun to accept only Bard needles. The jury found in favor of M3 Systems and against Bard on every question, and assessed compensatory damages, measured primarily as litigation costs, of $1.5 million, which were trebled as required by section 4 of the Clayton Act. Bard argues that the findings are not supported by substantial evidence, and that judgment as a matter of law should have been granted.

A. The Walker Process Claim

Fraud in obtaining a United States patent is a classical ground of invalidity or unenforceability ***1245** of the patent. In Walker Process, 382 U.S. 172, 147 USPQ 404 the Court established that antitrust liability under section 2 of the Sherman Act may arise when a patent has been procured by knowing and willful fraud, the patentee has market power in the relevant market, and has used its fraudulently obtained patent to restrain competition. Restraint on competition based on power in the relevant market must be established on the criteria of section 2, when the patent has been fraudulently obtained. See Nobelpharma, 141 F.3d at 1068, 46 USPQ2d at 1104 ; [FN7] Spectrum Sports, Inc. v. McQuillan, 506 U.S. 447, 455-56 (1993) (explaining Walker Process as requiring appraisal of the exclusionary power of the fraudulently obtained patent in terms of the relevant market for the product involved).

The jury found by special verdicts that the '056 and '308 patents were obtained by fraud in their prosecution before the PTO, as discussed in Part V, ante. The jury also found that "there is a relevant product market" for the biopsy guns and needles, together and separately, that Bard had monopoly power in each market and had "engaged in restrictive or exclusionary conduct with the conscious object of acquiring monopoly power in that market."

[9] It is not presumed that the patent-based right to exclude necessarily establishes market power in antitrust terms. See Abbott Labs. v. Brennan, 952 F.2d 1346, 1354, 21 USPQ2d 1192, 1199 (Fed. Cir. 1991) (possession of patent, and market advantages thus gained, do not establish antitrust market power). The virtually unlimited variety and scope of patented inventions and market situations militate against per se rules in these complex areas. Unless the patent had been obtained by fraud such that the market position had been gained illegally, the patent right to exclude does not constitute monopoly power prohibited by the Sherman Act. Walker Process, 382 U.S. at 177-78, 147 USPQ at 407 . As the Second Circuit stated in SCM Corp. v. Xerox Corp., "No court has ever held that the antitrust laws require a patent holder to forfeit the exclusionary power inherent in his patent the instant his patent monopoly affords him monopoly power over a relevant product market." 645 F.2d 1195, 1204, 209 USPQ 889, 899 (2d Cir. 1981).

[10] Thus it was necessary for M3 Systems to establish market power as well as fraudulent procurement of the patent and that Bard's related commercial activity was coupled with violations of section 2. In addition, applying the law of the Seventh Circuit to the elements of section 2, M3 was required to establish that Bard had a specific intent to monopolize, engaged in anti- competitive conduct, and had a dangerous probability of success. See Great Escape, Inc. v. Union City Body Co., 791 F.2d 532, 540 (7th Cir. 1986). These issues were argued at trial, and by special verdicts the jury found culpability on the part of Bard. However, in view of the incorrect verdicts on the question of fraud in procurement of the '056 and '308 patents, as discussed in Part V, as a matter of law the judgment of antitrust violation can not be sustained on Walker Process grounds.

B. "Sham" Litigation

Conduct prohibited under antitrust law includes

bringing suit to enforce a patent with knowledge that the patent is invalid or not infringed, and the litigation is conducted for anti-competitive purposes. In such events the antitrust immunity of Noerr -Pennington and California Motor Transp. Co. v. Trucking Unltd., 404 U.S. 508 (1972) does not apply to those who seek redress through judicial process.

The Supreme Court in Professional Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc. (PRE) established the two-part criteria of "sham" litigation: (1) the lawsuit must be objectively meritless such that "no reasonable litigant could expect success on the merits" and (2) it must be found that "the baseless lawsuit conceals 'an attempt to interfere directly with the business relationships of a competitor.' " 508 U.S. 49, 60, 26 USPQ2d 1641, 1646 (1993) (emphasis in original) (quoting Eastern R.R. Presidents Conf. v. Noerr Motor Freight, Inc., 365 U.S. 127, 144 (1961)). The Court declined to decide "whether and, if so, to what extent Noerr permits the imposition of antitrust liability for a litigant's fraud or other misrepresentations."PRE, 508 U.S. at 62 & n.6, 26 USPQ2d at 1646-47 & n.6. Fraud in the procurement of a patent is governed by Walker Process and, as in PRE, the complainant "must still prove a substantive antitrust violation."PRE, 501 U.S. at 61, 26 USPQ2d at 1646 .

***1246** Thus although sham litigation as a tactic to destroy competition can lead to antitrust violation, see U.S. Philips Corp. v. Sears Roebuck & Co., 55 F.3d 592, 597, 34 USPQ2d 1699, 1703 (Fed. Cir. 1995); cf. Handgards, Inc. v. Ethicon, Inc., 743 F.2d 1282, 1288, 223 USPQ 214, 222-23 (9th Cir. 1984) (addressing Noerr -Pennington issue and explaining that to invoke " sham" exception the claimant must show "some abuse of process," and requiring clear and convincing evidence of bad faith), sham litigation requires more than a failed legal theory. PRE, 508 U.S. at 60-61 & n.5, 26 USPQ2d at 1646 & n.5; see Carroll Touch, Inc. v. Electro-Mechanical Sys., Inc., 15 F.3d 1573, 1582, 27 USPQ2d 1836, 1844 (Fed. Cir. 1993).

[11] Neither the bringing of an unsuccessful suit to enforce patent rights, nor the effort to enforce a patent that falls to invalidity, subjects the suitor to antitrust liability. Cf. Concrete Unltd. Inc. v. Cementcraft, Inc., 776 F.2d 1537, 1539, 227 USPQ 784, 785 (Fed. Cir. 1985) (no liability for unfair competition based on suit to enforce an invalid patent). Since a principal purpose of the patent system is to provide innovators with a property right upon which investment and other commercial commitments can be made, absent the PRE criteria the patentee must have the right of enforcement of a duly granted patent, unencumbered by punitive consequences should the patent's validity or infringement not survive litigation. See id. The law recognizes a presumption that the assertion of a duly granted patent is made in good faith, see Virtue v. Creamery Package Mfg. Co., 227 U.S. 8, 37-38 (1913); this presumption is overcome only by affirmative evidence of bad faith. See PRE, supra%i.

M3 Systems states that Bard knew its patents were not infringed when it brought suit, citing the testimony of a Bard engineer that he did not think the original M3 needle infringed the '056 patent and that other Bard employees had told him that M3 changed its needle design to one that did not infringe. The engineer also testified that he did not know whether those who told him M3's needles did not infringe had ever read the '056 patent, or whether they were familiar with the concept of infringement under the doctrine of equivalents. This was the totality of the evidence of sham litigation concerning the '056 patent ; there was no evidence at all with respect to the '308 patent. [FN8] This does not constitute substantial evidence that this litigation was objectively meritless and brought in bad faith. The judgment of antitrust violation can not be upheld on sham litigation grounds.

C. Attempt to Monopolize [FN9]

M3 Systems proposed that Bard had modified its biopsy gun and needles for the purpose of preventing use of Tru-Cut needles and then to exclude M3's copies so that they did not fit the gun without an adapter. M3 contends that Bard's motives were anti-competitive, pointing to Bard documents showing internal discussions of competitive products and concern for patent scope and market share. Bard replies that the Tru-Cut was not suitable for its new gun because it could not achieve reverse motion, and points out that M3's witness acknowledged that M3 could effectively compete, as were several other producers of biopsy guns and needles.

Bard was under no duty to facilitate M3's competition by refraining from changing its products. The jury instructions did not distinguish patent-supported products and markets based thereon from

actions described to the jury as being in restraint of trade. For example, the jury instruction on intent to monopolize was as follows:

M3 Systems also alleges that it was injured by Bard's unlawful attempt to monopolize. An attempt to monopolize may be proven even if Bard lacks monopoly power, but because of its alleged exclusionary conduct, there exists a dangerous probability that Bard will obtain monopoly power in any market. In order to win on its claims of attempted monopolization, M3 Systems must prove each of the following elements by a preponderance of the evidence:

First, that Bard had a specific intent to achieve monopoly power in a relevant market; second, that Bard engaged in exclusionary or restrictive conduct in furtherance of its specific intent; third, that there ***1247** was a dangerous probability that Bard would obtain monopoly power in the relevant market; and, fourth, that M3 Systems was injured in its business or property by Bard's conduct.

In explaining further, the district court referred to "exclusionary or restrictive conduct" and "unreasonable acts and practices," again without reference to patented products and their status in the law. Although the court instructed that "conduct that involves the introduction of superior products" is not exclusionary or restrictive, the court also stated that "where conduct is ambiguous, direct evidence of a specific intent to monopolize may lead you to conclude that the conduct was intended to be and was in fact exclusionary or restrictive." No mention was made of the patentee's statutory right to exclude, and there was no instruction to consider that right.

These broadly stated descriptions of exclusionary or restrictive conduct, unlimited by the conditions set in Walker Process or PRE and taking no cognizance of the legal rights of the patent grant, do not rise to the level of violation of antitrust law. Thus I must, respectfully, dissent from the court's ruling that Bard incurred liability under the Sherman and Clayton Acts by its actions in modifying and improving its patented products, thereby requiring M3 to provide an adapter with its replacement needles for the Bard gun.

The panel majority on this issue holds that the jury verdict of monopoly power must be sustained, although the power held by Bard in this market is based on the patent right. Bard or its predecessor Radiplast changed from the Tru-Cut to a newly designed needle that was capable of reverse movement, thus facilitating removal, inspection, and reinsertion of the inner needle while the cannula remained in place. This needle assembly is the subject of the '056 patent. The record states that M3 was obliged to use an adapter to fit its existing needles to Bard's gun; that is the antitrust ill of which M3 complained. This does not, as a matter of law, present a jury question of violation of the Sherman Act. See California Computer Prods., Inc. v. International Bus. Mach. Corp., 613 F.2d 727, 744 (9th Cir. 1979) (when the innovation is an improvement, that it affects competition is not an antitrust violation, and no jury question arises).

Both the needle assembly alone and the integrated biopsy gun/needle device were patented. They were subject to Bard's patent-based rights to exclude others from making, using, or selling them. It was not Bard's changes to its biopsy gun or needles that affected M3's sale of replacement needles; it was the patents on these products. To hold that Bard could violate the Sherman Act by changing these products, if M3's business was adversely affected, is a novel and pernicious theory of antitrust law that is contrary to the principles of competition, and fraught with litigation-generating mischief.

Despite this court's recent affirmation in Virginia Panel Corp. v. MAC Panel Co., 133 F.3d 860, 873-74, 45 USPQ2d 1225, 1236 (Fed. Cir. 1997) that "a patentee may lawfully police a market that is effectively defined by its patent," this court now holds that changing and improving one's proprietary product that has created its own market niche, if to a competitor's potential disadvantage, is actionable under the Sherman Act. The competition-favoring rule is that an innovator has no duty to help its competitors: "It is the possibility of success in the marketplace, attributable to superior performance, that provides the incentives on which the proper functioning of our competitive economy rests."Berkey Photo, Inc. v. Eastman Kodak Co., 603 F.2d 263, 281 (2d Cir. 1979). In California Computer the court observed that " [IBM] was under no duty to help CalComp or other peripheral equipment manufacturers survive or expand." 613 F.2d at 744. This court has today created a new, vague, and unworkable cause of action, of clear public detriment, with no balancing public benefit.

The concept that antitrust law should bar an

innovator from making changes or improvements to its products, when others may be affected thereby, is not brand new. However, cases where this issue has been litigated have been of a different order of competitive impact than here asserted; and I have found no case in which such a charge has been sustained. In In re IBM Peripheral EDP Devices Antitrust Litig., 481 F. Supp. 965, 1002-05 (N.D. Cal. 1979), aff'd sub nom. Transamerica Computer Co. v. International Bus. Mach. Corp., 698 F.2d 1377 (9th Cir. 1983), cited by the panel majority, the district court declined to assess liability for IBM's interface changes that prevented use of competitors' peripheral devices when "the contested changes were improvements in the products, were not unreasonably restrictive of competition, and hence did not violate the Sherman Act."Id. at 1382.

A basic premise of patent law, and antitrust law in general, is that the commercial advantage gained by new technology, and its statutory protection by patent, do not convert the possessor thereof into a prohibited monopolist. In United States v. Grinnell ***1248**(Cite as: 48 U.S.P.Q.2d 1225, *1248) Corp., 384 U.S. 563, 570-71 (1966) the Court distinguished the willful acquisition or maintenance of monopoly power from "growth or development as a consequence of a superior product, business acumen, or historic accident."See also Jefferson Parish Hospital District No. 2 v. Hyde, 466 U.S. 1, 37 n.7 (1984) ("A common misconception has been that a patent or copyright, a high market share, or a unique product that competitors are not able to offer suffices to demonstrate market power.") (O'Connor, J., concurring); A.I. Root Co. v. Computer/ Dynamics, Inc., 806 F.2d 673, 676 (6th Cir. 1986) (rejecting "any absolute presumption of market power for copyright or patented product").

When the market for new technology is protected by patent, to violate the antitrust law there must be an improper use of the patent right, "coupled with violations of Section 2."Walker Process, 382 U.S. at 177-78, 147 USPQ at 407 . In Walker Process the Court again explained that a patent does not of itself establish a presumption of market power in the antitrust sense. Id. at 178, 147 USPQ at 406 . In American Hoist & Derrick Co. v. Sowa & Sons, Inc., 725 F.2d 1350, 1367, 220 USPQ 763, 776 (Fed. Cir. 1984), this court wrote that "patent rights are not legal monopolies in the antitrust sense of the word." Yet in the case now before us the jury was asked to determine simply whether Bard had monopoly power in a relevant market, without reference to whether the "exclusionary conduct" of which M3 complained was the conduct of the patent law.

M3 did not allege the elements of an antitrust violation when patents are involved. See, e.g., Double D Spotting Service, Inc. v. Supervalu, Inc., 136 F.3d 554, 558 (8th Cir. 1998) (" 'The essential elements of a private antitrust claim must be alleged in more than vague and conclusory terms to prevent dismissal of the complaint on a defendant's [Rule] 12(b)(6) motion.' ") (quoting Crane & Shovel Sales Corp. v. Bucyrus-Erie Co., 854 F.2d 802, 805 (6th Cir. 1988)); Okusami v. Psychiatric Institute of Washington, Inc., 959 F.2d 1062, 1065 (D.C. Cir. 1992) (" [T]he plaintiff's antitrust claims, lacking the essential element of an agreement, were properly dismissed for failure to state a claim upon which relief could be granted.") Dismissal for failure to state a claim was the proper response to M3's undifferentiated assertion of anticompetitive practices.

I need not elaborate on the litigation opportunity affecting innovation-based industry, that is here so casually enabled. "Where competitors' products must interface with the monopolist's product the monopolist's introduction of a new product that makes that interconnection more difficult or expensive might violate Section 2, although no court has specifically so held." 1 American Bar Assoc., Antitrust Law Developments 286 (4th ed. 1997) (emphasis added). As a sister circuit recently stated, "Antitrust scholars have long recognized the undesirability of having courts oversee product design, and any dampening of technological innovation would be at cross-purposes with antitrust law." United States v. Microsoft Corp., 147 F.3d 935, 948 (D.C. Cir. 1998).

The proceedings at trial, and the jury instructions, made no mention of the patent rights here present. It is without precedent to find antitrust liability premised on a theory that development of new products is illegally anticompetitive when the new product requires competing suppliers to adjust their product accordingly. Commentators who have considered the question of "whether product innovation can ever be unlawfully 'predatory' " have concluded that "no administrable rule could be fashioned that would not exact an unreasonably heavy toll." 3 Phillip E. Areeda & Herbert Hovenkamp, Antitrust Law Section 705b (rev. ed. 1996). If this court deems it appropriate to add this burden to patent-based innovation, there should at least be some overriding

public benefit. However, antitrust jurisprudence has well understood that the enforcement of the antitrust laws is self-defeating if it chills or stifles innovation. See IBM Peripherals, supra%i.

Neither the jury instructions nor the special interrogatories framed a charge of predatory conduct that comports with established criteria of antitrust liability. It appears that this charge at trial was cobbled together from left- over allegations of bad acts by bad actors. Indeed, M3's antitrust counterclaims mention only Walker Process fraud and sham litigation, which all members of this panel agree were not established. I can not discern, in the law or in the record of this case, either legal or factual support for this new form of antitrust liability.

VII

MISUSE; OTHER ISSUES

The defense of patent misuse arises from the equitable doctrine of unclean hands, and relates generally to the use of patent rights to obtain or to coerce an unfair commercial advantage. Patent misuse relates primarily to a patentee's actions that affect competition in unpatented goods or that otherwise ***1249** extend the economic effect beyond the scope of the patent grant. See Mallinckrodt, Inc. v. Medipart, Inc., 976 F.2d 700, 703-04, 24 USPQ2d 1173, 1176 (Fed. Cir. 1992) ("The concept of patent misuse arose to restrain practices that did not in themselves violate any law, but that draw anticompetitive strength from the patent right, and thus were deemed to be contrary to public policy.")

Patent misuse is viewed as a broader wrong than antitrust violation because of the economic power that may be derived from the patentee's right to exclude. Thus misuse may arise when the conditions of antitrust violation are not met. See Zenith Radio Corp. v. Hazeltine Research, Inc., 395 U.S. 100, 140-41, 161 USPQ 577, 597 (1969). The key inquiry is whether, by imposing conditions that derive their force from the patent, the patentee has impermissibly broadened the scope of the patent grant with anticompetitive effect. See Virginia Panel Corp. v. MAC Panel Co., 133 F.3d 860, 868, 45 USPQ2d 1225, 1231-32 (Fed. Cir. 1997); B. Braun Medical, Inc. v. Abbott Labs., 124 F.3d 1419, 1426, 43 USPQ2d 1896, 1902 (Fed. Cir. 1997); Mallinckrodt, 976 F.2d at 704, 24 USPQ2d at 1176 .

The jury returned special verdicts that Bard had misused both the '056 and '308 patents. Patent misuse arises in equity, and a holding of misuse renders the patent unenforceable until the misuse is purged; it does not, of itself, invalidate the patent. See Morton Salt Co. v. G. S. Suppinger Co., 314 U.S. 488 [52 USPQ 30] (1942); Senza-Gel Corp. v. Seiffhart, 803 F.2d 661, 668 n.10, 231 USPQ 363, 368 n.10 (Fed. Cir. 1986). When a jury has determined that patent misuse occurred we review the underlying findings of fact for support by substantial evidence, presuming that the jury resolved any factual disputes in favor of the verdict winner. We then determine whether, on the found or presumed facts, the conclusion on the issue of misuse is correct. See Virginia Panel, 133 F.3d at 868, 45 USPQ2d at 1231-32 .

The jury instruction on patent misuse was focussed primarily on the charge that Bard was attempting to enforce the patents against goods known not to be infringing, the court explaining that antitrust violation is not necessary to find misuse if patents have been used "wrongfully" to exclude competitors:

A patent is unenforceable for misuse if the patent owner attempts to exclude products from the marketplace which do not infringe the claims of the patent and the patent owner has actual knowledge that those products do not infringe any claim of the patents. The patent is also unenforceable for misuse when a patent owner attempts to use the patent to exclude competitors from their marketplace knowing that the patent was invalid or unenforceable.

A patent will not be rendered unenforceable for misuse if the patent owner has enforced the patent in the good faith belief that the accused products infringed the patent's claims.

You may consider all aspects of the conduct of the patent owner in deciding whether a patent has been misused. In order to find misuse, you may not determine that -- you need not determine that an antitrust violation has been proved. Even if an antitrust violation has not been proven, you may still find that the patents have been misused if you conclude that the patents have been used wrongfully.

This instruction calls to mind the view expressed in USM Corp. v. SPS Techs., Inc., 694 F.2d. 505, 510, 216 USPQ 959, 963 (7th Cir. 1982) that the misuse doctrine is "too vague a formulation to be useful."

Although the defense of patent misuse indeed evolved to protect against "wrongful" use of patents, the catalog of practices labelled "patent misuse" does not include a general notion of "wrongful" use. See id. ("in application, the doctrine has largely been confined to a handful of specific practices").

M3 Systems did not propose any of the classic grounds of patent misuse, such as tying or enforced package licensing or price restraints or extended royalty terms, see Chisum, supra, Section 19.04 [3], but generally urged the view that Bard's actions, even if not illegal, were an improper use of patents. Although the law should not condone wrongful commercial activity, the body of misuse law and precedent need not be enlarged into an open-ended pitfall for patent- supported commerce.

[12] There was no evidence that Bard's competitive activities were either per se patent misuse or that they were not "reasonably within the patent grant."See Mallinckrodt, 976 F.2d at 708, 24 USPQ2d at 1180 . The conduct to which the jury instruction on misuse generally refers, that is, "wrongful" enforcement of patents, is activity protected under Noerr and California Motor, and is not subject to collateral attack as a new ground of "misuse." M3 Systems adduced no evidence of patent misuse other than was presented for its antitrust claims. It is not patent misuse to bring suit to enforce patent rights not fraudulently obtained, nor is otherwise legal competition such behavior as to ***1250** warrant creation of a new class of prohibited commercial conduct when patents are involved.

The verdicts of patent misuse are not supported by evidence or correct legal theory. The judgment on these verdicts is reversed.

Other Arguments/Issues

We have not discussed every minor argument and issue raised in this appeal. All have been considered, and we have discussed those of relevance. With respect to Bard's frequent references to jury prejudice resulting from disclosure to the jury of Bard's recent civil penalties and criminal convictions for several violations of Food and Drug Administration laws and regulations, we take note that no motion for a new trial was made on this ground, and the issue is not before us for review.

Costs

No costs.

AFFIRMED IN PART, REVERSED IN PART, VACATED IN PART, AND REMANDED.

Mayer, C.J., concurring-in-part and dissenting-in-part.

I join the court's opinion as it pertains to the validity and infringement of the '308 patent, and agree that the jury's verdict on fraud cannot stand. I join Judge Bryson's opinion sustaining the jury verdict on M3's antitrust counterclaim and remanding. My views on the validity of the '056 patent follow.

By special interrogatory, a jury found each of the disputed claims of the '056 patent invalid because the claimed invention was on sale in the United States more than one year before July 30, 1986, the filing date of the '056 patent's parent application. M3 Systems presented the jury with two reasons why the invention may be invalid for violation of the on sale bar: a transfer from Radiplast to Pharmaseal of 250 needles in June 1985 and an offer from Radiplast to Dr. Ronald Phelps in November 1984. We may affirm the invalidity verdict on either basis. See, e.g., Ethicon Endo-Surgery, Inc. v. United States Surgical Corp., 93 F.3d 1572, 1582, 40 USPQ2d 1019, 1027 (Fed. Cir. 1996). Because I believe that the jury had substantial evidence that Radiplast placed the invention claimed in the '056 patent on sale in November 1984, I would sustain the jury's verdict of invalidity.

Discussion

An inventor who places his invention "in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States" loses his right to patent the invention. 35 U.S.C. Section 102(b) (1994). A determination that a product was placed on sale under section 102(b) is a question of law, based on underlying facts. See, e.g., KeyStone Retaining Wall Sys. Inc. v. Westrock, Inc., 997 F.2d 1444, 1451, 27 USPQ2d 1297, 1303 (Fed. Cir. 1993). While we review the trial court's ultimate determination of a section 102(b) bar de novo, see, e.g., Ferag AG v. Quipp, Inc., 45 F.3d 1562, 1566, 33 USPQ2d 1512, 1515 (Fed. Cir. 1995); U.S. Environmental Products Inc. v. Westall, 911 F.2d 713, 715, 15 USPQ2d 1898, 1900 (Fed. Cir. 1990), in considering its denial of Bard's motion for

judgment as a matter of law, we review the jury's verdict, as did the trial court, for substantial evidence. See, e.g., Shatterproof Glass Corp. v. Libbey-Owens Ford Co., 758 F.2d 613, 619, 225 USPQ 634, 636 (Fed. Cir. 1985); Railroad Dynamics, Inc. v. A. Stucki Co., 727 F.2d 1506, 1513, 220 USPQ 929, 936 (Fed. Cir. 1984). "'Substantial' evidence is such relevant evidence from the record taken as a whole as might be accepted by a reasonable mind as adequate to support the finding under review."Perkin-Elmer Corp. v. Computervision Corp., 732 F.2d 888, 893, 221 USPQ 669, 673 (Fed. Cir. 1984).

We are guided in our review of the legal conclusion by principles underlying the on sale bar: broad and prompt disclosure of inventions to the public; providing opportunity to experiment, improve, and determine the market value of inventions; discouraging inventors from withdrawing inventions that the public has already come to believe are freely available; and discouraging commercialization that expands the patent system's grant of the right to exclude others. See, e.g. Envirotech Corp. v. Westech Eng'g, Inc., 904 F.2d 1571, 1574, 15 USPQ2d 1230, 1232 (Fed. Cir. 1990); King Instrument Corp. v. Otari Corp., 767 F.2d 853, 860, 226 USPQ 402, 407 (Fed. Cir. 1985); General Electric Co. v. United States, 654 F.2d 55, 61, 211 USPQ 867, 873 (Ct. Cl. 1981). Because the ultimate determination of whether an on sale bar exists rests on the totality of the circumstances, that is, on consideration of the unique facts of each transaction or event, no one factor necessarily controls. See, e.g., Ferag, 45 F.3d at 1566, 33 USPQ2d at 1515 . Nevertheless, we have held that " [f]oremost among these is the policy of preventing inventors ***1251** from exploiting the commercial value of their inventions while deferring the beginning of the statutory term. To this end, the inventor is strictly held to the requirement that he file his patent application within one year of any attempt to commercialize the invention." Ferag, 45 F.3d at 1566, 33 USPQ2d at 1515 (internal citation omitted). The inventor is entitled to the full benefit of the patent regime; the public is entitled to full, timely disclosure of the protected invention.

We are likewise guided in our review by the principle that we must presume facts necessary to support the jury verdict. See, e.g., Perkin-Elmer, 732 F.2d at 893, 221 USPQ at 673 ; Railroad Dynamics, 727 F.2d at 1516, 220 USPQ at 939 . Given the on sale bar verdict, we assume the jury found that Radiplast made a definite offer to sell certain subject matter and that this subject matter "fully anticipated the claimed invention or would have rendered the claimed invention obvious by its addition to the prior art."UMC Elec. Co. v. United States, 816 F.2d 647, 656, 2 USPQ2d 1465, 1472 (Fed. Cir. 1987); see also LaBounty Mfg., Inc. v. United States Int'l Trade Comm'n, 958 F.2d 1066, 1071, 22 USPQ2d 1025, 1028 (Fed. Cir. 1992). Thus, on review we must affirm the verdict of invalidity of the '056 patent if these factual findings are supported by substantial evidence, and within the context of the various policies underlying the on sale bar, the totality of circumstances supports the ultimate legal conclusion.

I. Offer for Sale

On September 25, 1984, Ronald Phelps, an Alabama medical doctor, sent Radiplast AB a letter that stated: "I am interested in learning more about the new device for percutaneous needle biopsy pictured on the enclosed brochure. I would appreciate it if you would send me all the information you have pertaining to the instrument. Also, please include a price list. Thank you." Phelps included with this letter a brochure entitled "Radi-biospy device, a new device for percutaneous needle biopsy." This brochure described previously existing technology and then stated:

A new device has been constructed in order to improve this biopsy method. With the aid of this instrument the biopsy procedure can be carried out with one hand, and as the movements of the obturator and cannula are automatized, better tissue specimens are obtained. All biopsies can be performed by one examiner under dynamic ultrasonic control, or under fl [uo]roscopy.

The new device consists of a spring-trigger system for firing the two different parts of the needle -- the cannula and the obturator.

It is constructed of alloyed brass and, like the pressure rod, can be autoclaved.

See special instructions before using.

Manufactured by . . . RADIPLAST AB. . . .

By way of its managing director, Thomas Engstrom, Radiplast, replied as follows to Phelps' letter on November 12, 1984:

We thank you for your letter of [S]ept. 25 [,] 1984 and for your interest in our BIOPSY DEVICE. I am truly sorry for my late reply.

Our generation No. 2 of the device will we, together with our new biopsy needles suitable for the device, start marketing in USA beginning of __85, at the moment we do not know through which company. If you do not want to wait until we have our representation in USA arranged, you can allways [sic] order the device directly from us.

Our price for the device is SEK 9.900, -- and for the needles SEK 75, -- /ea.

The device is reusable and can be autoclaved. Very little service has to be done on the device due to reliable design. The needles are dispo [s]able and are designed to suit the device.

I am enclosing leaflet and article.

I am looking forward to hearing from you.

(Emphasis added).

The Radiplast brochure that Phelps sent to Radiplast describes a device that can be operated with one hand, by one operator, leaving the physician's other hand free to operate the ultrasound or fluoroscopy equipment. The brochure describes both parts of the needle as automatized by way of a spring-trigger system. It describes the construction materials used to manufacture the device as well as a procedure by which it can be cleaned. In short, the brochure can be understood to describe either a first generation prior art device or the second generation device described in the '056 patent.

Despite this ambiguity, Engstrom's reply to Phelps' letter in November 1984 is far more telling both in what it said and when it said it. His letter explicitly refers to the second generation device and "new biopsy needles suitable for the device." Since the second generation device requires a needle that moves both forward and rearward, unlike the prior art TruCut needle, Engstrom's letter is a clear offer for sale of the second ***1252** generation device and new biopsy needles. With the exception of a reference to marketing efforts being made in the United States and the possibility of sales through a United States distributor thereafter, this letter was written entirely in the present tense.

The letter was also written after a series of correspondence between Radiplast and Hart Enterprises, a United States medical device manufacturer, addressing tooling and manufacturing costs for these new biopsy needles. On September 4, 1984, Engstrom had written: "Enclosed please find . . . a drawing on the biopsy needle. The stainless steel parts are not the final ones, there could be changes in length, diam. and the design of the point." On September 28, 1984, Hart Enterprises responded: " [E]nclosed are two drawings, one of the Stylet Hub and one of the Cannula Hub for your Radiplast Biopsy Needle. If you approve these concepts we will proceed to make a prototype, and then production of the molds." Radiplast replied on October 18, 1984: "Biopsy needles: Enclosed please find our order for tooling and engineering. We approve your design of the plastic parts. The dimension from the top surface to center line of both cannula and stylet should be 4.2 mm. Regarding the needles we will probably start with 2.000 -- 3.000 units bulk packed." Less than one month later, Engstrom sent Phelps the November 12, 1984, letter.

These facts alone are sufficient support for the jury's verdict that there was a definite offer for sale of something more than the TruCut prior art or first generation needles. However, to apply the on sale bar, the jury also had to decide whether this offer for sale of new biopsy needles was an offer of the invention claimed in the '056 patent. We review this second presumed factual finding for substantial evidence, and like the district court on its denial of Bard's motion for judgment as a matter of law, we also consider whether there may be policy considerations against imposing the on sale bar.

II. Offer of the Claimed Invention

Bard claims that Radiplast's November 1984 offer to sell second generation devices and new biopsy needles cannot trigger the bar because at that time no operable device had been made, FDA approval had not been obtained, Radiplast had not conducted clinical testing, it had not found a United States distributor, and it had not developed a final needle design. Bard misapprehends the legal significance of each of these. Clinical testing is not required before a sale can bar patent rights. Nor can subsequent clinical testing excuse a prior sale, if what was offered for sale was the claimed invention. Clinical testing is merely one possible policy reason why a particular sale might be

excused from the bar. Since Radiplast did not contemplate sales to Engstrom for testing purposes, the possibility of subsequent clinical testing is of no moment. Likewise, FDA approval is not required before a sale can bar patent rights. Even an illegal sale of the claimed invention before the critical date can bar patent rights. Nor is a domestic distributor relevant to the on sale bar inquiry; a sale by a foreign distributor, from a foreign country to the United States can bar patent rights. See, e.g., In re Vaceney, 761 F.2d 671, 676-77, 226 USPQ 1, 4 (Fed. Cir. 1985).

The first of Bard's two remaining arguments -- that no operable device had been made -- is a feint because manufacture of an operable device is not a prerequisite for application of the on sale bar. See, e.g., Barmag Barmer Maschinenfabrik AG v. Murata Machinery, Ltd., 731 F.2d 831, 837, 221 USPQ 561, 565 (Fed. Cir. 1984). While operability may or may not be relevant, see, e.g., UMC, 816 F.2d at 656, 2 USPQ2d at 1472 (reduction to practice is not a requirement for application of the on sale bar), manufacture of an operable device alone is not, see, e.g., Continental Plastic Containers v. Owens Brockway Plastic Products, Inc., 141 F.3d 1073, 1078-79, 46 U.S.P.Q.2d 1277, 1281 (Fed. Cir. 1998) (declining to extend exception from public use bar under section 102(b) in design patent case). Operability is relevant only to the extent it demonstrates that a claimed element of the invention had not yet been invented, or the inventors did not know they had a workable invention and thus had nothing to offer for sale. See, e.g., Petrolite Corp. v. Baker Hughes, Inc., 96 F.3d 1423, 1427, 40 USPQ2d 1201, 1204 (Fed. Cir. 1996) (" [T]he thrust of the on-sale inquiry is whether the inventor thought he had a product which could be and was offered to customers, not whether he could prevail under the technicalities of reduction to practice . . . ." (quoting Paragon Podiatry Lab., Inc. v. KLM Lab., Inc., 984 F.2d 1182, 1187 n.5, 25 USPQ2d 1561, 1570 n.5 (Fed. Cir. 1993)). Bard has not asserted the second circumstance, and as explained below, the alterations made after the offer for sale to Phelps did not address inventive aspects of the '056 patent's new biopsy needle.

As support for its remaining contention -- that it had not developed the final design of the biopsy needle -- Bard points to Engstrom's testimony, as managing director of Radiplast, and correspondence between Radiplast,*1253 American Pharmaseal, (one of Radiplast's potential distributors in the United States), and Alan Taylor (president of Hart Enterprises). Each of these letters was sent after the November 1984 offer for sale to Phelps, and each evidences continued testing of and proposed modifications to the second generation device and the new biopsy needles. [FNa1]

Engstrom testified that American Pharmaseal's research and development laboratories conducted in-house testing. A technical report produced after this testing says that "testing [was] to insure functionality of the spring loaded activatior, the Biopty(trade mark) device, and the needle before releasing them to the field trial." As a result of its testing, American Pharmaseal recommended: "increas [ing] the strength of the stylet handle design and add [ing] the buffing operation to cannula grinding process." Engstrom testified that this advice was "to, how do you say, make some changes on the plastic parts and also the -- what do you call that -- well, the, for some plastic parts broke actually, so we put some, a stopper in the second generation device to prevent, if that happened, to prevent the stylet to go further on." Engstrom testified that on American Pharmaseal's advice, Radiplast added a "stop" to the second generation device, after the offer to Phelps.

Engstrom also testified that Radiplast conducted field trials in December 1985, from which it learned that "there was a potential risk for this one snapping back and hurt the doctor's hand," and "many patients thought the noise of the instrument was very disturbing." As a result, Radiplast added "an automatic retraction, a spring, actually, which took this handle back," and "some damping things, you know, to reduce the noise of the instrument." After these field trials, Engstrom sent a letter to Hart Enterprises on January 15, 1985, which stated: "The needle should be changed according to our phone discussion, which means that the wings of the cannula hub should have the same length. Both should be as long as the shortest wing." A letter from Hart Enterprises to Engstrom on January 25, 1985, enclosed three drawings that show " [t]he cannula and stylet hub dimensions are identical to the drawings and prototype you had previously received, with the exception that the cannula hub wings are now [sym]metrical."

This evidence suggests that Radiplast modified the second generation device by altering the strength of the stylet handle design, adding a buffing operation to the cannula grinding process, a stopper, automatic

retraction via a spring, damping to reduce noise, and equal length symmetrical cannula hub wings as long as the shortest wing. However, Bard cannot avoid the on sale bar merely by showing improvements to the invention after its commercialization. See, e.g., Seal-Flex, Inc. v. Athletic Track and Court Constr., 98 F.3d 1318, 1324, 40 USPQ2d 1450, 1454-55 (Fed. Cir. 1996). These changes must be something more than obvious mechanical adjustments; they have to be inventive redesigns that are claimed by the '056 patent . While some of Radiplast's changes resulted in different possible embodiments of, or additions to, the new biopsy needle that is claimed by the '056 patent, none of the changes are claimed in the text of the '056 patent. Moreover, contrary to Bard's contentions, its evidence suggests at the very least that Radiplast had "reason to expect" in November 1984, that its needle "would work for its intended purpose upon completion,"Micro Chemical, Inc. v. Great Plains Chemical Co., Inc., 103 F.3d 1538, 1545, 41 USPQ2d 1238, 1244 , and that Radiplast had more than a mere conception from which it was working towards development, see UMC, 816 F.2d at 657, 2 USPQ2d at 1472 .

Because Bard's evidence shows nothing beyond unclaimed mechanical adjustments to the needle design claimed in the '056 patent after the November 1984 offer for sale of new biopsy needles, the jury had substantial evidence in support of its finding that the November 1984 offer for sale generated a statutory bar. See, e.g., Robotic Vision Sys., Inc. v. View Eng'g, Inc., 112 F.3d 1163, 1167, 42 USPQ2d 1619, 1623 (Fed. Cir. 1997). A contrary view would attribute to the '056 patent additional limitations taken from later developed commercial embodiments. Because the claimed invention had been completed, Engstrom's new biopsy needle design calls for an outcome different from Robotic Vision, 112 F.3d 1163, 42 USPQ2d 1619 (remanded for further fact finding on the completion date of a computer software program), Micro Chemical, 103 F.3d at 1544, 41 USPQ2d at 1243 (only a proposed configuration existed and the invention remained to be completed), and Shatterproof Glass, 758 F.2d at 623, 225 ***1254** (Cite as: 48 U.S.P.Q.2d 1225, *1254) USPQ at 640 (a reasonable jury could have found that " apparatus and method of the claims were not functional").

III. Policy Considerations

Other than the need for sufficient time to test the new biopsy needle design, which is not a policy consideration summoned by the November 1984 offer, Bard has not argued that there are policy considerations weighing against imposition of the on sale bar. Since the policies that underlie the bar focus on the inventors attempts to exploit the invention, not whether a potential purchaser was made aware of or understood it, discussion of Phelps' actual knowledge of the details of the invention or the differences between generations of the biopsy gun is irrelevant. See, e.g., Ferag, 45 F.3d at 1568, 33 USPQ2d at 1516 ("We emphasize that this is an objective test, and that at its heart lies the inventor's attempt to commercialize the invention . . . . [T]he measure of the bar is what was offered, not the patentee's intent.") In light of the strong policy of preventing exploitation of the commercial value of an invention while deferring commencement of the statutory term, I would affirm the jury's application of the on sale bar.

Bryson, J., concurring in part and dissenting in part.

I concur in the portion of the court's opinion upholding the jury's verdict of non-infringement of the '308 patent. I also concur in the portions of the court's opinion reversing the district court's judgment that the '308 patent is invalid, and overturning the jury's verdict on the issue of fraud. Accordingly, I join parts II-V, VI.A-B, and VII of Judge Newman's opinion.

With respect to portions of the judgment relating to the '056 patent, I agree with Chief Judge Mayer that the '056 patent is invalid under the "on- sale bar" of 35 U.S.C. Section 102(b), although I take a somewhat different analytical path to that conclusion, as discussed below. Because I conclude that the '056 patent is invalid based on the on-sale bar, I do not reach the other grounds on which the jury found the '056 patent invalid.

Finally, Chief Judge Mayer and I agree that the jury verdict on M3's antitrust counterclaim must be affirmed. Because we do not uphold all of the grounds on which the jury found liability, however, we conclude that the jury may have improperly assessed damages on liability grounds that cannot stand. We therefore must remand for further proceedings to determine the proper amount of damages to be assessed on the antitrust counterclaim.

I

With respect to the on-sale bar, I believe that the June 1985 sale of 250 needles from Radiplast to Pharmaseal was sufficient to support the jury's verdict that the asserted claims of the '056 patent were rendered invalid by a sale more than one year before July 30, 1986, the effective filing date of the patent. It is undisputed that the needles sold in June 1985 embodied the invention of the '056 patent. Whether that sale was sufficient to invoke the on-sale bar turns on whether the sale falls within the "experimental purpose" exception to the on-sale bar.

A

In the summer of 1984, Radiplast began looking for a company "to distribute and promote the sales of [its] biopsy instruments in the United States." Pharmaseal, a potential distributor of the instruments, sent a telex to Radiplast stating that "before any formal purchasing plans can be made," it would have to conduct field trials "to determine the performance and specimen quality of your biopsy device and disposable needle." Pharmaseal sent letters to several hospitals in December 1984 inviting them to participate in a "field trial as a potential sales/distribution system for Radiplast devices."

Radiplast responded by telex on January 21, 1985, setting a price for the needles to be used in Pharmaseal's field trial and offering large-quantity discounts for batches of up to 50,000 needles. Radiplast's telex stated that "in order to be able to deliver both needles and instruments in beginning of March [1985], we need a [telex] order, preferably this week." It also stated that "we have to meet and discuss more in detail all things related with the marketing of our biopsy instrument in U.S." With respect to Pharmaseal's proposed field trial, Radiplast merely suggested that "if you would like [Dr. Lindgren, the inventor] to visit the hospitals performing the trial, in order to help them get started, he will be happy to help you."

Pharmaseal agreed to purchase the instruments and, on March 28, 1985, placed an order for 10 biopsy guns and 250 needles from Radiplast. The instruments were shipped in June 1985. It is undisputed that the June 1985 transaction constituted a sale and that the needles sold at that time embodied the invention of the '056 patent.

Pharmaseal conducted in-house testing of the devices in July 1985 before releasing the ***1255** products to hospitals for the field trials. Following the in-house testing, Pharmaseal reported only minor problems and made minor manufacturing suggestions, such as recommending that Radiplast strengthen the stylet hub design and add a buffing operation to the cannula grinding process.

Although Bard contends that Dr. Lindgren attended some of the field trials and that Radiplast "was continually advised by Pharmaseal of [their] progress," Dr. Lindgren testified that he did not exercise any control over the tests, that he did not recall ever seeing the instrument used during a test, and that he did not receive or maintain any data from the tests. Bard appears to concede that the test results were not maintained in confidence, and it points to no evidence showing that the primary purpose of the tests was to ensure that the claimed features of the invention would operate as intended.

The field testing was performed at the behest of Pharmaseal, the purchaser, not Radiplast or the inventor. Pharmaseal "assumed primary responsibility" for the tests, while Radiplast merely "had an ongoing interest" in the progress of the trials and "was kept informed" of the progress of the field trials. During the field trials, Pharmaseal and Radiplast continued to discuss market potential, potential prices and volumes, and an instructional videotape to teach proper use of the instruments.

B

Bard argues that the jury verdict cannot stand because the in-house testing at Pharmaseal and the hospital field trials show that the sale was for experimental testing purposes. The so-called "experimental testing" exception to the on-sale bar applies only if commercial exploitation is "merely incidental to the primary purpose of experimentation to perfect the invention." Barmag Barmer Maschinenfabrik AG v. Murata Mach., Ltd., 731 F.2d 831, 839, 221 USPQ 561, 567 (Fed. Cir. 1984). In determining whether the inventor made the sale in question for purposes of determining whether the invention would work for its intended purpose, a court must consider various factors, such as the amount of control the inventor exercised over the testing; the length of the test period; whether any payment was made; whether there was a secrecy obligation; whether progress records were kept; whether someone other than the inventor conducted the experiments; and the degree of commercial

In Continental, however, this court noted that "no sales were ever made"; there was a joint development project between two companies to develop the invention; and the project was "cloaked in confidentiality." 948 F.2d at 1269-70, 20 USPQ2d at 1750 . Because the circumstances in Continental are so different from the circumstances in this case, Continental is of no help to Bard.

C

Bard also contends that the Pharmaseal sale cannot constitute a bar under 35 U.S.C. Section 102(b) because Radiplast did not make a profit on the transaction. The jury heard testimony, however, suggesting that Radiplast made a 60% profit on the Pharmaseal sale. Even ignoring any actual profit on the devices used in the field trials, it is clear that the Pharmaseal transaction was made primarily to develop a market for future sales, not primarily to test the claimed invention. At any rate, the failure to turn a profit is not determinative. "A patent owner may have created an on-sale bar despite losing money on a sale."U.S. Envtl. Prods., Inc. v. Westall, 911 F.2d 713, 717, 15 USPQ2d 1898, 1902 (Fed. Cir. 1990).

II

In support of its antitrust counterclaim, M3 presented three theories to the jury: (1) that Bard committed fraud in the procuring its patents (the Walker Process theory); (2) that Bard acted in bad faith in enforcing its patents (the "sham litigation" theory), and (3) that Bard modified its Biopty gun for the purpose of preventing its competitors' needles from being used in that gun. Bard challenges the sufficiency of the evidence to support the jury's verdict on each of those three theories. The panel is unanimous in concluding that the evidence is insufficient to support liability on the Walker Process and "sham litigation" theories. Chief Judge Mayer and I agree, however, that there is sufficient evidence to affirm the jury's antitrust liability verdict based on Bard's gun modification program, for the reasons set forth below.

A

The jury considered evidence that Bard modified its Biopty gun to prevent its competitors' non-infringing, flangeless needles from being used in Bard's guns. By special verdicts, the jury found that there was a relevant product market for replacement needles for fully automated reusable biopsy guns, that Bard had monopoly power in that market, and that it had acquired or maintained its monopoly power in that market through restrictive or exclusionary conduct.

[13] ***1257** In order to prevail on its claim of an antitrust violation based on Bard's modification of its Biopty gun to prevent the use of competing replacement needles, M3 was required to prove that Bard made a change in its Biopty gun for predatory reasons, i.e., for the purpose of injuring competitors in the replacement needle market, rather than for improving the operation of the gun. See In re IBM Peripheral EDP Devices Antitrust Litig., 481 F. Supp. 965, 1002 (N.D. Cal. 1979), aff'd sub. nom. Transamerica Computer Co. v. International Bus. Mach. Corp., 698 F.2d 1377 (9th Cir. 1983); see generally 1 ABA, Antitrust Law Developments 286-87 (4th ed. 1997). Bard argues that the evidence showed that absent patent protection for Bard's devices, M3 could still compete in the relevant market. While the evidence of Bard's market power was in dispute, the jury specifically found that Bard enjoyed monopoly power in the market for replacement needles. The evidence was sufficient to support the jury's verdict on that point and also to support the jury's conclusion that Bard maintained its monopoly position by exclusionary conduct, to wit, modifying its patented gun in order to exclude competing replacement needles.

The dissent on this issue starts from the premise that the modification to Bard's Biopty gun was an "improvement" and argues from that premise that to hold Bard liable for the modification would have the "pernicious" effect of penalizing innovators for making improvements to their products. The dissent's premise, however, is contrary to the jury's verdict, which was supported by the evidence. Although Bard contended at trial that it modified its Biopty gun to make it easier to load and unload, there was substantial evidence that Bard's real reasons for modifying the gun were to raise the cost of entry to potential makers of replacement needles, to make doctors apprehensive about using non- Bard needles, and to preclude the use of "copycat" needles. One internal Bard document showed that the gun modifications had no effect on gun or needle performance; another internal document showed that the use of non-Bard needles in the gun "could not possibly result in injury to either the patient or the physician." In view of that evidence, the jury could

"the [PTO] determined that the transfers to American Pharmaseal [ ] were for primarily experimental purposes and therefore did not trigger the bar," the record citations do not relate to this statement.

FN7 In Nobelpharma the Federal Circuit held in banc that Federal Circuit law would thenceforth apply to determination of whether fraudulent conduct occurred in obtaining a patent, whereas determination of the other elements of the section 2 violation, viz. market power in the relevant market and illegal restraints on competition, since not unique to the patent right would continue to be governed by regional circuit law. 141 F.3d at 1067-68, 46 USPQ2d at 1104 .

FN8 M3 in its brief states that: "The Jury specifically found that BARD had 'actual knowledge' that M3 did not infringe its patents or that the patents were invalid. [A10096; 11-3 Paragraphs 6,11]." There is no specific finding in the verdict form of "actual knowledge." The cites to Paragraphs6 & 11 are to the jury's finding of patent misuse, and the jury instructions at A10096 concern the duty of candor to the PTO. The source of the quoted "actual knowledge" is not given. Such misdirections are not helpful to the appellate tribunal; see also note 6, supra.

FN9 The court has affirmed the district court's judgment of antitrust violation on this ground; see the separate opinion of Judge Bryson, joined by Chief Judge Mayer. This section contains the dissenting opinion of Judge Newman.

FNa1 Reliance on Engstrom's trial testimony is inherently less reliable than contemporaneous documentary evidence. Cf. TP Lab., Inc. v. Professional Positioners, Inc., 724 F.2d 965, 972, 220 USPQ 577, 583 (Fed. Cir. 1984) (inventor's expressions of "subjective intent . . . particularly after institution of litigation, is generally of minimal value").

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48 U.S.P.Q.2d 1225

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reasonably conclude that Bard's modifications to its guns constituted "restrictive or exclusionary conduct" in a market over which it had monopoly power.

The dissent also takes issue with the jury instructions, contending that they failed properly to frame a charge of predatory conduct that comports with established criteria of antitrust liability. Because Bard did not challenge the court's instructions, however, the legal sufficiency of the jury charge on the antitrust issues is not properly before us on appeal. To be entitled to relief based on asserted errors in the court's instructions to the jury, Bard was required to challenge those instructions in this court and demonstrate that it timely objected to those instructions in the district court. Bard did neither, but instead based its argument entirely on the sufficiency of the evidence. Because the evidence is sufficient to support the verdict on the gun modification theory of liability, the jury's liability verdict must stand. See Mangren Research & Dev. v. National Chem. Co., 87 F.3d 937, 942 n.3 (7th Cir. 1996); Composite Marine Propellers, Inc. v. Van Der Woude, 962 F.2d 1263, 1265 (7th Cir. 1992).

B

While we affirm Bard's liability on the antitrust counterclaim, that does not necessarily mean that the jury's damage award of $1.5 million can be sustained. M3 presented evidence of three different markets (guns, guns and needles, and replacement needles) in which Bard allegedly caused antitrust injury, and the jury found Bard liable for injury in each market. The damages portion of the verdict, however, merely indicated a general award of $1.5 million without attribution to a particular market or exclusionary practice.

M3's evidence concerning Bard's gun modification program was relevant only to the replacement needle market. Because we have concluded that the evidence concerning Bard's activities in the other two markets cannot support antitrust liability, the question arises as to whether the $1.5 million damages award can be supported solely on the basis of the injury Bard's actions caused to M3 in the replacement needle market. That issue was not briefed on appeal, and the record, so far as we can ascertain, does not provide clear guidance as to the proper allocation of damages due to the injury suffered by M3 in the injury replacement needle market. Consequently, we vacate the antitrust damages award and remand to the district court to consider, after additional hearing or limited retrial, if necessary, the proper amount of damages attributable to Bard's gun modification program. See MCI Communications Corp. v. American Tel. & Tel. Co., 708 F.2d 1081, 1166-67 (7th Cir. 1983).

FN1 C.R. Bard, Inc. v. M3 Sys., Inc., No. 93-CV-4788 (N.D. Ill. Oct. 2 & Dec. 20, 1995) (orders).

FN2 Section 102. A person shall be entitled to a patent unless--

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, . . .

FN3 Section 102 A person shall be entitled to a patent unless--

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, . . .

FN4 This section is the dissenting opinion of Judge Newman. The court affirms the judgment of invalidity for violation of the on-sale bar, in separate opinions of Chief Judge Mayer and Judge Bryson.

FN5 The three different views in the three opinions of this panel on the on-sale issue point up the need for a more certain law than today exists. Inventors and those who commercialize inventions should reasonably know when the on-sale bar starts to accrue, instead of awaiting litigation-borne post hoc judicial evaluations of the totality of the circumstances, varying with the nature of the invention, the nature of the customer contact, and the judicial weight given to the conflicting policy interests.

I favor, as simple and fair, the bright line rule that for the Section 102(b) on-sale bar to accrue the invention must exist in commercial form when the offer of sale is made. This rule would implement the dominant policy of providing a one-year grace period for determining the performance of the product in the marketplace.

FN6 The record provided us does not show any response from the PTO. Although Bard states that

exploitation during the tests in relation to the purpose of the experimentation. Baker Oil Tools, Inc. v. Geo Vann, Inc., 828 F.2d 1558, 1564, 4 USPQ2d 1210, 1214 (Fed. Cir. 1987). Certain factors, such as the requirement that the inventor control the testing, that detailed progress records be kept, and that the purported testers know that testing is occurring, are critical to proving experimental purpose. Lough v. Brunswick Corp., 86 F.3d 1113, 1120, 39 USPQ2d 1100, 1105 (Fed. Cir. 1996) ("if the inventor has no control over the alleged experiments, he is not experimenting"); see generally 2 Donald S. Chisum, Patents Section 6.02[7][c] (1998).

The evidence shows that Radiplast's primary purpose in making the sale to Pharmaseal was to market the patented invention through Pharmaseal, not to conduct tests to determine whether the claimed invention would work for its intended purpose. Neither the in-house testing at Pharmaseal nor the field trials at hospitals were conducted under the control or supervision of the inventor or Radiplast; instead, the tests were proposed, controlled, and monitored by Pharmaseal, the purchaser. Dr. Lindgren, the inventor, admitted at trial that he had no control over the field trials, that he did not maintain any test data, and that he did not recall receiving any test results. Radiplast was not aware of the identity of the patients in the field tests, the organs that were being biopsied, or the types of tests being performed; indeed, the patients were apparently not even informed that the biopsies were being conducted as part of a test. The hospitals participating in the field trials were told that the trials were intended as "a potential sales/distribution system for Radiplast devices." There is no evidence that any secrecy agreements were made with Pharmaseal, the hospitals, or any of the test participants. Finally, it is undisputed that Pharmaseal paid for the instruments and needles used in the tests. All of these factors point away from the conclusion that the sale was made for purposes of experimentation. See Western Marine Elecs., Inc. v. Furuno Elec. Co., 764 F.2d 840, 846, 226 USPQ 334, 339 (Fed. Cir. 1985) (no experimental use where evidence pointed to market testing rather than experimentation).

Significantly, at the time of the sale of 250 needles in June 1985, Radiplast had an open offer to sell large quantities of needles to Pharmaseal at bulk discount prices. The January 21, 1985, telex had offered batches of up to 50,000 needles for a specific price, and smaller quantities of 10,000 and 20,000 needles for somewhat higher prices. The offer of such large quantities of needles was clearly for commercial, rather than experimental, ***1256** purposes, and by June 1985 it was clear that the needles that were being offered to Pharmaseal embodied the later-claimed invention. The bulk purchase offer provides further evidence that the June 1985 sale was not for experimental purposes. See Seal-Flex, Inc. v. Athletic Track & Court Constr., 98 F.3d 1318, 1325, 40 USPQ2d 1450, 1455 (Fed. Cir. 1996) (Bryson, J., concurring) ("if the sale or offer in question embodies the invention for which a patent is later sought, a sale or offer to sell that is primarily for commercial purposes and that occurs more than one year before the application renders the invention unpatentable"). Thus, it appears that Radiplast was marketing the later-claimed needles commercially at least by late June 1985. Its willingness to sell smaller quantities of needles to Pharmaseal to use in its field tests was evidently an accommodation to Pharmaseal, which conducted its own tests before distributing the needles to hospitals and doctors. The fact that Radiplast recognized that Pharmaseal intended to test the needles before distributing them in bulk, however, did not make Radiplast's offer and sale in 1985 any less commercial in nature.

The facts of this case are analogous to those in U.S. Environmental Products, Inc. v. Westall, 911 F.2d 713, 15 USPQ2d 1898 (Fed. Cir. 1990). In Westall, this court affirmed a district court's conclusion that a patent was invalidated by a sale more than one year before the filing date. That conclusion was based primarily on (1) the lack of written progress records and the failure to adhere to a testing schedule; (2) the inventor's failure to maintain control over the testing; and (3) promotion of the invention during the testing. Id. at 717-18. In this case, as in Westall, the evidence shows that neither the in-house tests at Pharmaseal nor the field tests at hospitals were under the control of the inventor or his company. There is little or no evidence of any written progress records; indeed, the inventor was apparently never provided with any test results. Finally, the communications between Radiplast and Pharmaseal throughout the purported testing period emphasized commercial sales and projections, not controlled experimentation.

Bard relies heavily on Continental Can Co. USA, Inc. v. Monsanto Co., 948 F.2d 1264, 20 USPQ2d 1746 (Fed. Cir. 1991), for the proposition that providing price estimates for future sales does not otherwise vitiate the experimental testing exception.

Decisions of the United States Courts and of the United States Patent and Trademark Office in Patent, Trademark, and Copyright Cases

Court of Appeals, Federal Circuit

Scripps Clinic & Research Foundation v. Genentech Inc.

Nos. 89-1541, -1542, -1543, -1646, -1647

Decided March 11, 1991

PATENTS

1. Patentability/Validity — Specification — In general (§115.1101)

Open-ended claims are not inherently improper; rather, their appropriateness depends upon particular facts of invention, disclosure, and prior art, and they may be supported if there is inherent, albeit not precisely known, upper limit and if specification enables one of skill in art to approach that limit.

2. Infringement — Defenses — Fraud or unclean hands (§120.1111)

Finding of intent is essential as matter of law to ruling of inequitable conduct, and such inequitable conduct must be deliberate and proved by clear and convincing evidence; thus, federal district court erred by granting summary judgment of inequitable conduct in view of court's own statement that its finding was "without implying improper motives" to inventors.

JUDICIAL PRACTICE AND PROCEDURE

3. Procedure — Summary judgment — In general (§410.3301)

Fact that both parties moved for summary judgment does not of itself establish that no disputed issue of fact exists and thus does not require that summary judgment be granted.

PATENTS

4. Practice and procedure in Patent and Trademark Office — Reissue — Error without deceptive intent (§110.1303)

Error of law is not excluded from class of error subject to correction in accordance with reissue statute, 35 USC 251, and, although attorney error is not open invitation to reissue in every case in which it may appear, purpose of statute is to avoid forfeiture of substantive rights due to error made without intent to deceive; statutory standard of reissuable error is objective, and does not require proof of subjective state of mind, nor does statute require showing that error in claiming product could not have been avoided, and thus inventors who established that they had claimed less than they had right to claim, that they had done so in error, and that there was no deceptive intention are entitled to reissue.

5. Patentability/Validity — Anticipation — In general (§115.0701)

JUDICIAL PRACTICE AND PROCEDURE

Procedure — Summary judgment — Patents (§410.3303)

Anticipation is question of fact, and finding of anticipation on motion for summary judgment requires federal district court to determine that no facts material to question are disputed, or that, even if all material factual inferences are drawn in favor of non-movant, there is no reasonable basis on which non-movant can prevail.

PATENTS

6. Patentability/Validity — Anticipation — In general (§115.0701)

Use of extrinsic evidence to explain reference's disclosure is sometimes appropriate, in order to show what reference meant to persons of ordinary skill in art, but is necessarily of limited scope and probative value, since finding of anticipation requires that all aspects of claimed invention were already described in single reference, and such finding would not be supportable if it is necessary to prove facts beyond those disclosed in reference in order to meet claim limitations; if it is necessary to reach beyond boundaries of single reference to provide missing disclosure of claimed invention, proper ground is not anticipation under 35 USC 102 but obviousness under 35 USC 103.

7. Patentability/Validity — Anticipation — Prior publication (§115.0705)

JUDICIAL PRACTICE AND PROCEDURE

Procedure — Summary judgment — Patents (§410.3303)

Federal district court erred by granting summary judgment that claims were invalid for anticipation, based upon subject matter described in prior publication, since apparent inconsistencies among three declarations filed by publication's author raise questions of credibility and weight and thus were improperly resolved on summary judgment, and since, in patent cases, questioning by affidavit is disfavored and is inadequate substitute for trial with witnesses, who are subject to examination and cross-examination in presence of decision-maker.

PATENTS

8. Patentability/Validity — Specification — Best mode (§115.1107)

Compliance with best mode requirement is question of fact, and invalidity for failure of compliance requires proof by clear and convincing evidence that inventor knew of, and concealed, better mode of carrying out invention than was set forth in specification.

9. Patentability/Validity — Specification — Best mode (§115.1107)

Failure of inventor, of claims for process of purifying blood clotting factor VIII:C, to voluntarily place in depository antibody which was used in carrying out claimed process is not sufficient to warrant finding of invalidity for failure to comply with best mode requirement, since Patent and Trademark Office did not require such deposit during examination of patent either initially or on reissue, since no protestor raised issue of deposit in connection with reissue application, and since failure to make deposit voluntarily cannot constitute legal or factual basis for patent invalidity.

10. Infringement — Doctrine of equivalents — Reverse equivalents (§120.0703)

Federal district court erred by granting summary judgment of infringement of claims for process of purifying blood clotting factor VIII:C, in view of questions of scientific and evidentiary fact raised by accused infringer that could produce sufficient ground for invoking doctrine of reverse equivalents.

11. Infringement — Defenses — Fraud or inequitable conduct (§120.1111)

Reference which was considered by examiner cannot be deemed to have been withheld by applicant even if examiner discovered it "on his own."

12. Practice and procedure in Patent and Trademark Office — Prosecution — Duty of candor — In general (§110.0903.01)

Infringement — Defenses — Fraud or inequitable conduct (§120.1111)

Applicant has absolute right to decline to do work suggested by Patent and Trademark Office, and to withdraw claims presented for examination, without incurring liability for inequitable conduct.

13. Infringement — Construction of claims (§120.03)

Patent construction — Claims — Process (§125.1309)

Correct reading of product-by-process claims, for infringement purposes, is that they are not limited to product prepared by process set forth in claims, since, for purposes of determining patentability, product is not limited by process stated in claims, and since claims must be construed in same way for validity and for infringement.

Particular patents — Chemical — Blood clotting factor

4,361,509 (Re. 32,011), Zimmerman and Fulcher, ultrapurification of Factor VIII using monoclonal antibodies, summary judgment of invalidity and infringement rev rsed.

Appeal from the U.S. District Court for the Northern District of California,

Schwarzer, J.; 3 USPQ2d 1481, 6 USPQ2d 1018, 11 USPQ2d 1187, and 12 USPQ2d 1157.

Consolidated patent infringement actions filed by Scripps Clinic & Research Foundation, Revlon Inc., and Rorer Group Inc. against Genentech Inc. and Miles Inc., and against Chiron Corp. From federal district court decision granting summary judgment on issues of invalidity and infringement, plaintiffs and Genentech cross-appeal. Affirmed in part, reversed in part, vacated in part, and remanded.

William S. Feiler, of Morgan & Finnegan, New York, N.Y. (Eugene Moroz, Patricia S. Rocha, and Bruce A. Pokras, of Morgan & Finnegan, with him on briefs; Stephen V. Bomse, of Heller, Ehrman, White & McAuliffe, San Francisco, Calif., of counsel), for plaintiffs-appellants.

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Arnold Sprung, of Sprung, Horn, Kramer & Woods (Nathaniel D. Kramer and Alan J. Grant, of Sprung, Horn, Kramer & Woods, with him on brief), New York, N.Y., for Miles Inc.

William L. Anthony, of Townsend & Townsend (Noemi C. Espinosa, of Townsend & Townsend, of counsel), Palo Alto, Calif., for Chiron Corp.

Before Markey * and Newman, circuit judges, and Beer, district judge.†

Newman, J.

This litigation concerns a substance called human Factor VIII:C, a complex protein that occurs naturally in normal blood and is essential to the clotting of blood. The patent in suit, United States Reissue Patent No. 32,011 (the "R'011" patent), is entitled "Ultrapurification of Factor VIII Using Monoclonal Antibodies", inventors Theodore S. Zimmerman and Carol A. Fulcher. Assigned to Scripps Clinic and Research Foundation, it was licensed exclusively to Revlon, Inc. Subsequent to the filing of this suit Revlon sold its interest to Rorer Group, Inc.

By appeal and cross-appeal, the parties [1] raise various issues of patent validity and enforceability, infringement and inducement to infringe, and reissue law and practice, all of which were decided on motions for summary judgment. Each side challenges the decision of certain issues adverse to it, and the final judgment based thereon.[2]

The Invention

Factor VIII:C, called the clotting or procoagulant factor, is found in all mammals, although it differs among species. It has been the subject of extensive scientific research, over many years. At the time the claimed invention was made, it was known that human Factor VIII:C is a complex protein produced by the Factor VIII:C gene and secreted into the blood stream. It occurs in normal blood plasma (plasma is the fluid fraction of blood) at a concentration of about 200 nanograms per milliliter. The total protein content of plasma is about 70 milligrams (0.070 gram) per milliliter; since a nanogram is one billionth of a gram, the total protein in plasma is 350,000 times greater than the Factor VIII:C protein in plasma. Most of the problems faced by researchers attempting to isolate Factor VIII:C were due to the amount and nature of the other proteins in the plasma.

It was known that in normal blood Factor VIII:C exists in complex association with another protein, named the "von Willebrand factor" or Factor VIII:RP (RP means "related protein"). The weight ratio of Factor VIII:C to Factor VIII:RP in normal blood is about 1:100.

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* Circuit Judge Markey vacated the position f Chief Judge on June 27, 1990.

† The Honorable Peter Beer, United States District Court for the Eastern District f Louisiana, sitting by designation.

[1] The plaintiffs will be grouped as "Scripps" unless otherwise stated. The defendants will be grouped as "Genentech" unless otherwise stated.

[2] These consolidated appeals and cross-appeals arise from judgments and orders of the United States District Court for the Northern District of California. *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 666 F.Supp. 1379, 3 USPQ2d 1481 (N.D. Cal. 1987); *Scripps Clinic and Research Foundation v. Genentech, Inc.*, 678 F.Supp. 1429, 6 USPQ2d 1018 (N.D. Cal. 1988) (on reconsideration); *Scripps Clinic and Research Foundation v. Genentech, Inc.* 707 F.Supp. 1547, 11 USPQ2d 1187 (N.D. Cal. 1989); and *Scripps Clinic and Research Foundati n v. Genentech, Inc.*, 724 F.Supp. 690, 12 USPQ2d 1157 (N.D. Cal. 1989) (Order).

Before the invention here at issue was made, scientists had succeeded in concentrating the Factor VIII:C in plasma. This concentrate has been used to replace transfusions of whole blood in the treatment of hemophilia. The process was expensive and, because of the large volume of whole blood needed as starting material, the possibility of contamination and disease from impurities in the source blood, the large amount of extraneous plasma proteins in the concentrate, and the large volume of concentrate that still had to be administered to the patient, there has been a continuing search for improvement. The record reflects the difficulties, over decades of research, in isolating and studying Factor VIII:C. Scripps reports that Genentech's scientists had been working in the field and had not isolated human Factor VIII:C in sufficient purity and amount to conduct successful characterization experiments.

At the Scripps Clinic & Research Foundation, Dr. Zimmerman and Dr. Fulcher were studying Factor VIII:C from human and porcine blood. These scientists succeeded in isolating and, for the first time, characterizing Factor VIII:C, by a process of chromatographic absorption of the Factor VIII:C complex using monoclonal antibodies specific to Factor VIII:RP, followed by separation of the Factor VIII:C.[3] Monoclonal antibodies are produced by the cloned copies of a single hybridoma cell. A hybridoma is a hybrid cell that is immortal: that is, it does not die as do normal cells, but continues to reproduce clones that in turn produce a specific antibody. As described in the R'011 patent, the hybridoma was made by fusing a mouse spleen cell that produced the desired antibody to Factor VIII:RP, with a mouse cancer cell, which contributed the immortality. The patent describes the method of assay for clones producing antibodies to VIII:RP, their isolation, and preparation of the monoclonal antibodies for use as the immunoadsorbent.

The claimed process whereby the Factor VIII:C/VIII:RP complex is separated from the other materials in blood, followed by separation of the VIII:C from the VIII:RP, is described in the R'011 patent and was summarized by Scripps as follows:

> The first step involves the application of a solution containing Factor VIII complex (Factor VIII:C/Factor VIII:RP) to a column packed with agarose beads. Attached to the beads is a monoclonal antibody to Factor VIII:RP. The monoclonal antibody binds and immobilizes the Factor VIII:RP part of the Factor VIII complex while the non-Factor VIII materials simply pass through the column. A calcium salt solution is then applied to break the bond between the Factor VIII:C and the Factor VIII:RP. The Factor VIII:C is eluted from the column while the Factor VIII:RP remains bound to the antibody.

The procedure produces purified but dilute Factor VIII:C:

> After this first step the Factor VIII:C is highly purified, but dilute. A second step to concentrate the Factor VIII:C solution may then be performed. This involves absorbing the Factor VIII:C on an aminohexylagarose column. The Factor VIII:C on the aminohexyl column is then eluted with a very small amount of calcium salt solution, resulting in a highly concentrated solution of highly purified Factor VIII:C.

The potency and activity[4] of the fractions obtained by this technique were summarized by Scripps as follows:

> When the Factor VIII:C is eluted from either type of column it is collected serially in a number of small, individual portions called "fractions." When the Factor VIII:C is eluted from the monoclonal antibody column, for example, the initial fractions will have little VIII:C. The VIII:C increases as the Factor VIII:C is released. After the majority of Factor VIII:C has been released, the later fractions will contain decreasing amounts.
>
> Table I in the Zimmerman patent contains an analysis of two individual fractions.

[3] Drs. Zimmerman and Fulcher characterized the Factor VIII:C using a technique described as SDS-gel ("SDS" stands for sodium dodecyl sulfate) electrophoresis and production of a precipitating heterologous antibody. This work was reported in Fulcher and Zimmerman, *Proc. Nat'l Acad. Sci. USA* "Characterization of the Human Factor VIII Procoagulant Protein with a Heterologous Precipitating Antibody", Vol. 79, pp. 1648-52, March, 1982. It is not disputed that this is the first time that human Factor VIII:C was sufficiently pure to be characterized scientifically, and that the Zimmerman/Fulcher characterization is now the generally recognized "fingerprint" of Factor VIII:C.

[4] "Potency" refers to the amount of activity in a given volume of solution. For example, if 1000 units of Factor VIII:C activity were dissolved in 1 milliliter (ml) of water, the potency of the solution would be 1000 units/ml.

"Specific activity" refers to the number of units of activity for a given mass of protein. For example, if 1000 units of Fact r VIII:C activity were present in 1/2 milligram (mg) of protein, the specific activity would be 2,000 units/mg.

One "Unit" is defined as the activity present in 1 ml of normal plasma.

Patent Fraction 3 has a potency of 1172 units/ml and a specific activity of 2294 units/mg. Patent Fraction 4 is from another experiment and has a potency of 545 units/ml and a specific activity of 2370 units/mg.

Issues raised in this litigation concern purified Factor VIII:C and the reliability and reproducibility of the process, as these aspects relate to the validity, enforceability, and infringement of the R'011 patent claims.

The Claims

The claims in suit are product-by-process claims 13, 14, 17, 18, and 34, and product claims 24-29. Claim 13 is representative of the product-by-process claims:

13. Highly purified and concentrated human or porcine VIII:C prepared in accordance with the method of claim 1.

Claim 1 is:

1. An improved method of preparing Factor VIII procoagulant activity protein comprising the steps of

(a) adsorbing a VIII:C/VIII:RP complex from a plasma or commercial concentrate source onto particles bound to a monoclonal antibody specific to VIII:RP,

(b) eluting the VIII:C,

(c) adsorbing the VIII:C obtained in step (b) in another adsorption to concentrate and further purify same,

(d) eluting the adsorbed VIII:C, and

(e) recovering highly purified and concentrated VIII:C.

Product claims 24-29 were added by reissue, and are the focus of most of the controversy:

24. A human VIII:C preparation having a potency in the range of 134 to 1172 units per ml, and being substantially free of VIII:RP.

25. A human VIII:C preparation of claim 24, wherein the VIII:C concentration is at least 160,000 fold purified relative to VIII:C in plasma.[5]

26. A human VIII:C preparation of claim 24, wherein the ratio of VIII:C to VIII:RP is greater than 100,000 times the ratio in plasma.

27. A human VIII:C preparation of claim 24, wherein said VIII:C is isolated from VIII:C/VIII:RP and 90-100 percent of the VIII:RP has been removed.

28. A human VIII:C preparation having a specific activity greater than 2240 units/mg.

29. A human VIII:C preparation of claim 28 wherein the potency is in the range of 134 to 1172 units/ml.

Summary Judgment

Summary judgment is a useful procedural tool whereby an unnecessary trial is avoided when there are no material facts in dispute. However, summary proceedings are not intended to substitute for trial when it is indeed necessary to find material facts. *Meyers v. Brooks Shoe, Inc.*, 912 F.2d 1459, 1461, 16 USPQ2d 1055, 1056 (Fed. Cir. 1990) ("the factual dispute should be reserved for trial"). A factual question is material if a reasonable jury could return a verdict for the nonmoving party based at least in part on its determination of the factual question. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). In determining whether there is a genuine issue of material fact, the evidence must be viewed in the light most favorable to the opponent of the motion, *Poller v. Columbia Broadcasting System, Inc.*, 368 U.S. 464, 473 (1961), and doubts resolved in favor of the opponent. *Cantor, dba Selden Drugs Co. v. Detroit Edison Co.*, 428 U.S. 579, 582 (1976).

A motion for summary judgment must be supported with a sufficient showing to establish that there is no genuine issue of material fact and that the moving party is entitled to judgment as a matter of law. Fed.R.Civ.P. 56(c); *Celotex Corp. v. Catrett*, 477 U.S. 317, 325 (1986). The burden of establishing entitlement to summary disposition is with the movant, with due consideration to the burden of proof. *Id.* When a sufficiently supported motion has been submitted, the burden of coming forward and showing that there is a genuine issue of material fact shifts to the nonmovant. The Court has observed that "all that is required is that sufficient evidence supporting the claimed factual dispute be shown to require a jury or judge to resolve the parties' differing versions of the truth at trial." *Anderson*, 477 U.S. at 249 (quoting *First National Bank of Arizona v. Cities Service Co.*, 391 U.S. 253, 288-289 (1968)). However, "[i]f the evidence is merely colorable, or is not significantly probative, summary judgment may be granted". *Anderson*, 477 U.S. at 249-50 (citations omitted).

[5] "Fold purification" is the ratio of the specific activity of a protein sample to the specific activity of normal plasma. The Factor VIII:C specific activity of normal human plasma is known to be 0.014 units/mg. Thus the relationship is:

fold purification = specific activity/0.014.

For example, if a Factor VIII:C sample has a specific activity of 2240 units/mg, its fold purificati n value is 160,000. Stated an ther way, the sample is 160,000 times purer, as to Factor VIII:C, than normal plasma.

Scripps and Genentech both argue that certain issues that were decided summarily against each of them were not resolvable on summary judgment in favor of the other, if Rule 56 were correctly applied. We have concluded that the district court was correct in its determination, as to some of the issues in suit, that there were no questions of material fact; but not for all issues. For those issues that could indeed be decided summarily, we have reviewed the decision for correctness as a matter of law. For those issues on which summary judgment was inappropriately granted, we have reversed the grant and remanded for trial.

I

Inequitable Conduct and Enablement

On the basis of statements that the inventors made to the reissue examiner in connection with prosecution of the newly added product claims, issued as claims 24-29 of the R'011 patent, the district court granted Genentech's motion for summary judgment of unenforceability of the claims based on inequitable conduct.

Although the court did not hold the claims invalid for lack of enablement, the issues of enablement and inequitable conduct were intertwined. The "enablement" requirement is set forth in Title 35 as follows:

> *35 U.S.C. §112 ¶1.* The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same. . . .

The purpose of this provision is to assure that the inventor provides sufficient information about the claimed invention that a person of skill in the field of the invention can make and use it without undue experimentation, relying on the patent specification and the knowledge in the art. *See United States v. Telectronics, Inc.*, 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988), *cert. denied*, 109 S.Ct. 1954 (1989).

During prosecution of the reissue application the patent examiner had raised various questions under §112, relating to the purity of the Factor VIII:C that was the subject of the proposed product claims. Communications from the inventors covered such matters as the presence of fibrinogen and fibronectin and their removal by those skilled in the art; variations in chromatographic purification results; and the determination of purity using SDS-gels. The examiner requested a showing of the mathematical relationship between specific activity and fold purification, and ther data, which the inventors provided.

The reissue examiner's objection to the scope of the product claims was withdrawn on the inventors' response that they had obtained human Factor VIII:C at "levels closely approaching the theoretical limit". The inventors explained that the difference in fold purification of about 169,000 shown in Table I, and their calculation of the theoretical value of 357,000-fold, was 2-fold, from which the inventors stated that the "specification teaches those skilled in the art the production of essentially pure VIII:C." They explained that the removal of any remaining fibrinogen and fibronectin was within the skill of the art, when these impurities were identified. The examiner, apparently satisfied with the inventors' answers,[6] granted the reissue application with the added product claims as amended.

[1] The inventors distinguished the case of *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970), which held the open-ended claims there presented unpatentable for lack of enablement of "future compositions having potencies far in excess of those obtainable from his teachings plus ordinary skill". *Id.* at 839, 166 USPQ at 24. Open-ended claims are not inherently improper; as for all claims their appropriateness depends on the particular facts of the invention, the disclosure, and the prior art. They may be supported if there is an inherent, albeit not precisely known, upper limit and the specification enables one of skill in the art to approach that limit. *See Fisher, supra.*

While Genentech argues that the issue is whether the inventors misrepresented the purity of their Factor VIII:C, Scripps points out that the claims do not require 100% pure VIII:C. The product-by-process claims all refer to "highly purified and concentrated" VIII:C, and the product claims contain limitations that are met by less than 100% pure VIII:C: for example, that the VIII:C is "at least 160,000 fold purified relative to VIII:C in plasma" (claim 25), that "the ratio of VIII:C to VIII:RP is greater than 100,000 times the ratio in plasma" (claim 26), that the VIII:C product has a potency of 134-1172 units/ml (claim 24) or a specific activity of over 2400 units/mg (claim 28), and is substantially free of VIII:RP (claims 24-27).

[6] The sev ral def ndants herein all presented arguments to the examiner, in Protests filed during the reissue proceeding, on why th product claims should not be all wed.

Indeed, the district court did not find that all these claim limitations depended on the criticized representations about purity that were made to the examiner. However, the court found that the inventors' statements about the purity of the product were unsupported by evidence, and on this basis adjudged all the claims unenforceable for inequitable conduct.

The court referred to a Declaration by Drs. Zimmerman and Fulcher, during prosecution of the reissue application, that "we have achieved purified VIII:C at levels very near what we believe to be the theoretical values with the claimed process." The court found that "Drs. Zimmerman and Fulcher made crucial factual assertions, for the purpose of reversing the Examiner's initial rejection of the open-ended purity claims, for which they had no factual support." The court stated at the hearing that the inventors made statements about purity for which they did not have evidence:

> THE COURT: . . . and without implying improper motives it is an issue [purity] on which the inventors did not seem to have evidence but without evidence they created the — well, you say they made a square statement saying that almost always will you get pure VIII:C when, in fact, they didn't know that you would almost always get pure VIII:C.

The district court expressed its concern about the inventors' knowledge of the reliability of the process:

> THE COURT: Mr. Feiler, I'm not questioning that they got pure C, they have gotten lots of pure C. What they did not know was what is the probability of getting VIII:C every time you run one of these columns. What percentage of the fractions that come out will be pure VIII:C. They just didn't know.

This reasoning is reflected in the court's finding:

> [T]he undisputed evidence shows that (1) only some of the fractions appeared to be free of fibronectin while others were not, (2) the inventors were unable to quantify how much fibronectin the stream of the product from the column contained, and (3) the fraction on which the patent application (Table I) was based contained up to 50% fibronectin.

Scripps, 707 F.Supp. at 1557, 11 USPQ2d at 1196.

Scripps stated that the inventors' statements to the examiner were justified, that the inventors believed them to be correct, that there was evidence before the district court that the inventors obtained gels showing essentially pure Factor VIII:C, and that the inventors obtained immunological tests showing no evidence of fibronectin or fibrinogen. Scripps argued that the inventors had the good faith belief that they had enabled the preparation of pure Factor VIII:C, and referred to evidence of contemporaneous correspondence from Dr. Zimmerman to other scientists that "We believe that purification of the human VIII:C is essentially complete". There were declarations filed with the district court, of Dr. Katzmann (a scientist at Revlon) and Dr. Hrinda (a scientist at Rorer), that the inventors had obtained essentially pure Factor VIII:C. Dr. Katzmann also explained that Factor VIII:C activity can vary in samples having the same degree of purity; Genentech's data showed the same effect. There was deposition testimony on tests by Dr. Fulcher, showing no fibronectin.

Genentech asserts that the inventors deliberately withheld an analysis of the Table I material after the examiner requested it, and misrepresented that the impurities were "trace" when in fact the materials described in the specification contained 50% fibrinogen and fibronectin. Scripps responds that the requested analysis of the Table I material was indeed provided, that the examiner understood and was not misled by the inventors' statements about purity, that additional evidence showed that the representations made to the examiner were scientifically correct, and that, in all events, the statements were made in good faith.

The district court placed substantial weight on Dr. Zimmerman's deposition testimony that "trace contaminants" fibrinogen and fibronectin remained, that he "did not have numbers for upper limits", and that "[i]t is a trivial matter to remove the fibrinogen and fibronectin once they have been identified". The court commented that "Dr. Fulcher in her deposition was unable to quantify [the term 'essentially pure'] or the term 'highly purified' ", and remarked that it is "impossible to extrapolate from one or several Laurells [tests of a fraction of the column stream] as to the degree of purity of the entire output". The court criticized these scientific facts as legal inadequacies.

The court appeared to require greater scientific precision than did any of the scientists whose testimony was presented. The statute, however, is directed to persons of skill in the field of the invention. Indeed, Genentech provided no evidence that one of skill in the field of this invention could not make and use a product satisfying all the limitations of the claims, by following the inventors' disclosure and the knowledge of the art. Neither evidence nor expert opinion to this effect was offered.

[2] The materiality of a representation, and whether the representation was made with intent to deceive or mislead, are the two essential factual predicates to determination of inequitable conduct. *Modine Mfg. Co. v. Allen Group, Inc.*, 917 F.2d 538, 541, 16 USPQ2d 1622, 1624 (Fed. Cir. 1990). The district court stated that the "three elements of inequitable conduct" are "material prior information, chargeable to applicant, not disclosed to the PTO". *Scripps*, 707 F.Supp. at 1557, 11 USPQ2d at 1196. Notably missing is the element of intent, essential as a matter of law to a ruling of inequitable conduct. *See Kingsdown Medical Consultants, Ltd., v. Hollister, Inc.*, 863 F.2d 867, 876, 9 USPQ2d 1384, 1392 (Fed. Cir. 1988). Conduct that requires forfeiture of all patent rights must be deliberate, and proved by clear and convincing evidence. While Genentech argues that absence of reference by the court to intent does not mean that the court did not find intent, the court's remark that it was "without implying improper motives [to the inventors]" contravenes this argument. Even were the inventors' statements concerning purity in error, a finding of disputed fact that is not appropriate on summary judgment, the absence of a finding of intent to deceive or mislead the examiner precludes summary judgment of inequitable conduct. *See KangaROOS U.S.A., Inc. v. Caldor, Inc.*, 778 F.2d 1571, 1573, 228 USPQ 32, 35-36 (Fed. Cir. 1985) (a disputed question of intent to deceive is not appropriate for summary resolution).

The grant of partial summary judgment of unenforceability of the R'011 claims for inequitable conduct is reversed.

[3] Scripps had filed a cross-motion for summary judgment on this issue. This does not, of itself, require adjudication in its favor. *United States v. Fred A. Arnold, Inc.*, 573 F.2d 605, 606 (9th Cir. 1978); *accord, Cram v. Sun Insurance Office, Ltd.*, 375 F.2d 670, 673-74 (4th Cir. 1967) ("The fact that both sides moved for summary judgment does not establish that there is no issue of fact and require that judgment be granted for one side or the other"). These disputed factual questions of materiality and intent, which depend on the assessment of scientific facts as well as on the credibility of witnesses, are not amenable to summary resolution. The issue is remanded for trial.

II

35 U.S.C. §251

A

The R'011 patent is a reissue of Patent No. 4,361,509 ("the '509 patent"), granted on November 20, 1982. Genentech challenged the adequacy of the patentee's reason for seeking reissue, stating that this reason was insufficient in terms of 35 U.S.C. §251. On this ground the district court granted Genentech's motion for partial summary judgment of invalidity of claims 17, 18, 24-29, and 34.

Although there were factual aspects debated by the parties, they are not material to the question of the legal adequacy of the patentee's reason for requesting reissue. That is a question of law, and the facts material to that question were not in dispute. The matter could have been, and was, decided summarily. *See Paperless Accounting, Inc. v. Bay Area Rapid Transit Sys.*, 804 F.2d 659, 662, 231 USPQ 649, 651 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 933 (1987) ("These facts are not in dispute, though their legal significance is. Thus the basis on which the district court decided the question was amenable to summary judgment"). However, the district court erred in its conclusion of law.

The reissue statute provides in part:

> *35 U.S.C. §251.* Whenever any patent is, through error without any deceptive intention, deemed wholly or partly inoperative or invalid, by reason of a defective specification or drawing, or by reason of the patentee claiming more or less than he had a right to claim in the patent, the Commissioner shall . . . reissue the patent for the invention disclosed in the original patent, and in accordance with a new and amended application. . . . No new matter shall be introduced into the application for reissue.

In accordance with 37 C.F.R. §1.175(a)(5) and (a)(3) the applicant for reissue must "specify[ ] the errors relied upon, and how they arose or occurred," and must "distinctly specify[ ] the excess or insufficiency in the claims"; and in accordance with 37 C.F.R. §1.175(a)(6) the applicant must declare the absence of deceptive intention.

The principal error that the inventors sought to cure was the claiming of "less than [they] had a right to claim in the patent" due to the omission of product claims. The '509 patent contained only process and product-by-process claims.[7] In the reissue application inventors Zimmerman and Fulcher declared that they had always viewed the Factor VIII:C product as their invention, pointing out that the '509 specification stat-

[7] Broadened claims by reissue must be applied for within two years of grant of the riginal patent. 35 U.S.C. §251. This requirement was met.

ed that it was an object of their invention to produce highly purified Factor VIII:C.

[4] An error of law is not excluded from the class of error subject to correction in accordance with the reissue statute. Although attorney error is not an open invitation to reissue in every case in which it may appear, *see In re Weiler*, 790 F.2d 1576, 1579, 229 USPQ 673, 675 (Fed. Cir. 1986) ("not every event or circumstance that might be labeled 'error' is correctable by reissue"), the purpose of the reissue statute is to avoid forfeiture of substantive rights due to error made without intent to deceive. *See generally Ball Corp. v. United States*, 729 F.2d 1429, 1939 n.28, 221 USPQ 289, 296 n.28 (Fed. Cir. 1984) (the reissue statute "is based on fundamental principles of equity and fairness").

When the statutory requirements are met, reissuance of the patent is not discretionary with the Commissioner; it is mandatory ("shall"). *See In re Handel*, 312 F.2d 943, 948, 136 USPQ 460, 464 (CCPA 1963) ("the whole purpose of the statute, so far as claims are concerned, is to permit limitations to be added to claims that are too broad or to be taken from claims that are too narrow").

Genentech does not dispute that error was made, and does not challenge the principle of the availability of product claims to the purified Factor VIII:C. Further, Genentech does not assert that the attorneys' initial view of the unavailability of product claims involved any deceptive intention. The district court, holding that there was insufficient reason for reissue, appeared to interpret §251 as requiring a showing that the error in claiming the product could not have been avoided, in order to be eligible for cure. This is not the framework of the reissue statute.

The law does not require that no competent attorney or alert inventor could have avoided the error sought to be corrected by reissue. Failure of the attorney to claim the invention sufficiently broadly is "one of the most common sources of defects". *In re Wilder*, 736 F.2d 1516, 222 USPQ 369 (Fed. Cir. 1984), *cert. denied*, 469 U.S. 1209 (1985):

> An attorney's failure to appreciate the full scope of the invention is one of the most common sources of defects in patents. The fact that the error could have been discovered at the time of prosecution with a more thorough patentability search or with improved communication between the inventors and the attorney does not, by itself, preclude a patent owner from correcting defects through reissue.

Id. at 1519, 222 USPQ at 371.

Subjective intent is not determinative of whether the applicants erred in claiming less than they had a right to claim. *In re Mead*, 581 F.2d 251, 255, 198 USPQ 412, 416 (CCPA 1978). "Intent to claim" is not the criterion for reissue, and has been well described as "but judicial shorthand, signifying a means of measuring whether the statutorily required *error* is present." *In re Weiler*, 790 F.2d 1576, 1581, 229 USPQ 673, 676 (Fed. Cir. 1986) (emphasis in original). The statutory standard of reissuable error is objective, and does not require proof of subjective state of mind:

> Determining what protection [an inventor] intended to secure by [an] original patent for the purposes of §251 is an essentially factual inquiry confined to the *objective* intent manifested by the original patent.

In re Rowand, 526 F.2d 558, 560, 187 USPQ 487, 489 (CCPA 1975) (emphasis in original).

On undisputed facts, the inventors established that they had claimed less than they had a right to claim, that they had done so in error, and that there was not deceptive intention. The application for reissue fully complied with the statutory and regulatory requirements.[8]

As a matter of law, reissue claims 17, 18, 24-29, and 34 are not invalid on this ground. The grant of partial summary judgment is reversed. On remand, partial summary judgment shall be entered for Scripps on this ground.

B

The district court had also held the reissue product claims invalid for inadequate support in the specification for their open-ended scope, referring to changes that Drs. Zimmerman and Fulcher made in the text of the specification during the drafting process. For example, they changed "virtually pure" to "highly purified"; and inserted "largely" before "free of contaminants". This is an issue of enablement, which is not challenged by Genentech; but it also raises questions of claim interpretation in light of the specification. In view of the several disputed questions of material fact underlying these issues, see Part I *ante* and Part V *post*, summary judgment on this ground was improper, and the

[8] Th patent examiner and the PTO Office of Quality Review found that the applicant adhered to correct reissu practice, pursuant to Manual of Patent Examining Procedure §1456 (Rev. 3, 1986).

grant thereof is reversed. This issue, also, requires trial.

III

Anticipation

The district court held, on cross-motions for summary judgment, that "it had been proved by clear and convincing evidence" that claims 24, 26, and 27 were invalid for anticipation, 35 U.S.C. §102(b), based on subject matter described in a 1979 dissertation by Robert B. Harris entitled "Isolation and Characterization of Low Molecular Weight, Non-Aggregated Antihemophilic Factor from Fresh Human Plasma".

A

[5] Anticipation is a question of fact. *Shatterproof Glass Corp. v. Libbey-Owens Ford Co.*, 758 F.2d 613, 619, 225 USPQ 634, 637 (Fed. Cir.), *cert. dismissed*, 474 U.S. 976 (1985). To make such finding on summary judgment, the court must determine that no facts material to the question are disputed; or that even if all material factual inferences are drawn in favor of the non-movant, there is no reasonable basis on which the non-movant can prevail. *Cooper v. Ford Motor Co.*, 748 F.2d 677, 679, 223 USPQ 1286, 1288 (Fed. Cir. 1984). The standard of proof that would have to be met at trial must be considered. *Anderson*, 477 U.S. at 257.

Invalidity for anticipation requires that all of the elements and limitations of the claim are found within a single prior art reference. *Carella v. Starlight Archery and Pro Line Co.*, 804 F.2d 135, 138, 231 USPQ 644, 646 (Fed. Cir. 1986); *RCA Corp. v. Applied Digital Data Systems, Inc.*, 730 F.2d 1440, 1444, 221 USPQ 385, 388 (Fed. Cir. 1984). There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention.

[6] It is sometimes appropriate to consider extrinsic evidence to explain the disclosure of a reference. Such factual elaboration is necessarily of limited scope and probative value, for a finding of anticipation requires that all aspects of the claimed invention were already described in a single reference: a finding that is not supportable if it is necessary to prove facts beyond those disclosed in the reference in order to meet the claim limitations. The role of extrinsic evidence is to educate the decision-maker to what the reference meant to persons of ordinary skill in the field of the invention, not to fill gaps in the reference. *See Studiengesellschaft Kohle, mbH v. Dart Industries, Inc.*, 726 F.2d 724, 727, 220 USPQ 841, 842 (Fed. Cir. 1984) (although additional references may serve to reveal what a reference would have meant to a person of ordinary skill, it is error to build "anticipation" on a combination of these references). If it is necessary to reach beyond the boundaries of a single reference to provide missing disclosure of the claimed invention, the proper ground is not §102 anticipation, but §103 obviousness. Indeed, a publication on the Harris dissertation was included in the prior art statement filed by Scripps and was a cited reference under §103.

B

In the summary judgment proceedings the parties filed three successive declarations of Dr. Harris, each explaining his dissertation. In the first declaration, filed by Miles, Inc., Harris stated that he isolated "a low molecular weight antihemophilic factor". In his second ("supplemental") declaration, filed by Scripps, Harris described this factor as not a naturally occurring substance, and of low specific activity:

> 6. The material I identified as low molecular weight antihemophilic factor (LMW-AHF) was not a naturally occurring substance. The material of my dissertation is the result of reacting plasma with a reducing agent called dithiothreitol (DTT) prior to purification. The reduced plasma is run through an initial purification step, and is then chemically reacted with radioactively labeled iodoacetamide (^{14}C-IAA). This reduced and alkylated material was the LMW-AHF reported in my dissertation. After further purification, I obtained a maximum specific activity of 59.1 [units]/mg.

In the third Harris declaration, filed by Miles, Harris stated that his dissertation

> accurately reports on my work in which I was able to, and did, obtain a human VIII:C preparation having a potency of 193 [units]/ml and being substantially free of VIII:RP, the ratio of VIII:C to VIII:RP being greater than 100,000 times the ratio in plasma.

The third Harris declaration was cited by the district court in support of its finding of anticipation.

The parties debate whether Harris' statement in his second declaration that his product was chemically changed from naturally occurring VIII:C, is contradicted by the statement in his third declaration that he obtained a human VIII: C preparation. Scripps also points out that neither the po-

tency value nor the ratio of VIII:C to VIII:RP described in the third Harris declaration appears in the Harris dissertation. Nor does the gel pattern evidence on which the district court found that:

> Harris also based his identification of his preparation upon sodium dodecyl sulfate polyacrylamide gel electrophoresis (SDS-PAGE) tests [the same tests used by Dr. Fulcher]. While Harris' gel patterns do not match the gel pattern found by Dr. Fulcher, there is no evidence that if he had VIII:C, it would necessarily have the gel pattern found by Dr. Fulcher.

Scripps, 707 F.Supp. at 1551 n.6, 11 USPQ2d at 1190 n.6. Further, this finding that human Factor VIII:C, if obtained by Harris, would not necessarily have the "fingerprint" gel pattern of Dr. Fulcher, was not simply an adverse factual inference, improper on summary judgment; it was a finding of scientific fact contrary to the evidence. This finding also appears to be inconsistent with the court's finding that Dr. Harris had obtained purified Factor VIII:C because he based his identification on the same tests and gel patterns taught by Zimmerman and Fulcher. Also contradicting the court's conclusion was Scripps' evidence that the human Factor VIII:C SDS-gels of the inventors, the defendants, and non-parties to the litigation were the same, and that Dr. Harris' gel patterns were different.

Scripps contends that the court also erred in taking Dr. Harris' assertion in his third declaration that he obtained a potency of 193 units/ml and then construing the dissertation so as to find support for it. The court found support for this potency by combining (1) the potency of 2.7 units/ml reported by Harris for the sample in his Figure 9 with (2) the 71-fold concentration of an unidentified sample described on page 56 of the dissertation, and then multiplying 2.7 by 71 to obtain a potency of 191.7 units/ml. This combination of data is contrary to the statement of Dr. Harris in his second declaration that:

> 15. Neither is there any information from which to infer that the LMW-AHF recovered in the experiment represented by Figure 9 was the subject of [the page 56] lyophilization and reconstitution experiment.

Scripps also states that the maximum potency that the dissertation disclosed was 10 units/ml. Even crediting Dr. Harris' assertion that the ratio of AHF (antihemophilic factor) to VWF (von Willebrand factor) may have been as high as 100,000:1, Scripps calculated that this would only increase the potency of the concentrated sample on Harris' page 56 to a maximum of 10.0 units/ml. A sample having the potency of 191.7 units/ml, the value found by the district court, was calculated by Scripps to have a theoretical ratio of no less than 1,917,000:1, over 19 times higher than that asserted by Dr. Harris in his dissertation. Scripps thus argues that the court's findings are contrary to the evidence. We need not decide the correctness of these calculations and their premises, for it is clear that these issues, on which there was conflicting evidence, were not subject to summary resolution.

[7] To the extent that apparent inconsistencies among the three Harris declarations raise questions of credibility and weight, whether of witness or of interpretation of scientific data, they were improperly resolved on summary judgment. *Agosto v. INS*, 436 U.S. 748, 756 (1977); *Poller*, 368 U.S. at 473. In patent cases, questions by affidavit is disfavored. *See Poller v. Columbia Broadcasting System, Inc.*, 368 U.S. 464, 473 (1961); *United States v. Fred A. Arnold, Inc.*, 573 F.2d 605, 606 (9th Cir. 1978). Trial by document is an inadequate substitute for trial with witnesses, who are subject to examination and cross-examination in the presence of the decision-maker. *Sartor v. Arkansas Natural Gas Corp.*, 321 U.S. 620, 628 (1944).

Scripps also raised the question of whether the Harris dissertation was enabling and placed the purported anticipatory teaching of purified Factor VIII:C in possession of the public. Scripps pointed out that data in Harris' third declaration, on which the court relied, do not appear in his dissertation or in any other reference. *See Akzo N.V. v. United States Int'l Trade Comm'n*, 808 F.2d 1471, 1479, 1 USPQ2d 1241, 1245 (Fed. Cir. 1986), *cert. denied*, 482 U.S. 909 (1987) (anticipatory reference must be enabling); *In re Brown*, 329 F.2d 1006, 1011, 141 USPQ 245, 249 (CCPA 1964). The need to consider this issue, on disputed factual premises, also negates the propriety of the grant of summary judgment based on anticipation.

The grant of partial summary judgment of invalidity of claims 24, 26, and 27 for anticipation by the Harris dissertation is reversed. The issue is not amenable to summary disposition, and is remanded for trial.

IV

Best Mode

The district court granted Genentech's motion for summary judgment that claims 13, 14, 17, 18, 24-29, and 34 are invalid for failure to comply with the "best mode" requirement of 35 U.S.C. §112:

> *§112.* The specification shall . . . set forth the best mode contemplated by the inventor of carrying out his invention.

[8] Compliance with the best mode requirement is a question of fact, and invalidity for failure of compliance requires proof by clear and convincing evidence that the inventor knew of and concealed a better mode of carrying out the invention than was set forth in the specification. *See Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1369, 1379, 231 USPQ 81, 90 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987).

The concealment asserted by Genentech relates to the monoclonal antibodies that bind the Factor VIII complex in the initial step of separation from plasma. Genentech did not dispute that the specification describes the inventors' preferred method of obtaining these monoclonal antibodies. The specification describes the process, starting with injection into mice of the commercial Factor VIII concentrate, to produce antibodies against Factor VIII:RP; the preparation of the hybridomas and their screening for the desired antibodies; and the method of evaluation of the antibody's ability to bind Factor VIII:RP in the presence of salt solution that disassociates Factor VIII:C. The specification describes the properties for which the antibodies were screened, *viz.* to obtain a monoclonal antibody to Factor VIII:RP, of the IgG class, which binds greater than 90% of the VIII:RP out of plasma or concentrate, and which remains bound to the VIII:RP during saline elution of Factor VIII:C.

None of this was criticized by Genentech. There was no charge of concealment of special manipulations, or undisclosed techniques. Genentech's argument is primarily that because of the laborious nature of the process of screening monoclonal antibodies, the inventors should have voluntarily placed in a depository and made available to the public the antibody to Factor VIII:RP designated 2.2.9, which was the first effective antibody obtained by Scripps' screening, and was used by Scripps in carrying out the claimed invention.

Scripps states that the procedures in the specification produced monoclonal antibodies having the characteristics set forth in the specification, that the process of obtaining these antibodies was fully disclosed, that the data in Table I are for the 2.2.9 antibody, and that the 2.2.9 antibody was not concealed. Scripps agreed that the 2.2.9 antibody was indeed the first that had the described properties, and states that three out of the first seven antibodies screened had these properties, all obtained by routine and admittedly time-consuming procedures. It was not disputed that the inventors obtained the 2.2.9 antibody by following the procedures in the patent specification, and that these were the inventors' preferred procedures.

The district court found that the inventors concealed the 2.2.9 antibody, and that this antibody was the best mode of carrying out the invention. The court did not hold that deposit of the 2.2.9 antibody was required, although the court stated that a person of skill in the art would not have known "where to obtain it". The court made no other finding relating to concealment.

[9] A deposit was not required by the PTO during examination of either the '509 or the R'011 patents. *See* M.P.E.P. §608.01 (p)(C)(3). Nor does Genentech argue that deposit was obligatory. No protester raised the issue of deposit in connection with the reissue application. Although Genentech suggests that Scripps should have made a deposit voluntarily, failure to do so can not constitute legal or factual basis for patent invalidity.

Despite the extensive attorney argument, there were no material facts in dispute. There was no evidence by Genentech that the antibodies used by Drs. Zimmerman and Fulcher differed from those obtainable according to the process described in the specification. The laborious nature of this work was recognized in *Hybritech, supra*, and again in *In re Wands*, 858 F.2d 731, 737-38, 8 USPQ2d 1400, 1406-07 (Fed. Cir. 1988). In *Wands* this court, considering the question of enablement, declined to require the deposit of antibody samples that could be obtained by screening following the procedures in the specification.

Genentech had argued to the PTO, in its Protest against the reissue application, that the process is "easily" carried out to produce "high affinity monoclonal antibodies":

> [T]here are numerous references demonstrating the ease with which high affinity monoclonal antibodies could be obtained to Factor VIII:R[P].

In the context of best mode, on facts similar to those at bar, this court's holding in *Hybritech* settled the issue:

> The only evidence even colorably relating to concealment is testimony by various Hybritech employees that sophisticated, competent people perform the screening and that the screening process is labor-intensive and time-consuming. *It is not plausible that this evidence amounts to proof of concealment* f a best mode for screening or producing monoclonal anti-

bodies for use in the claimed '110 process, and therefore we are of the firm conviction that the district court's finding that the best mode requirement was not satisfied is clearly erroneous.

Hybritech, 802 F.2d at 1385, 231 USPQ at 94 (emphasis added). Applying *Hybritech* to the undisputed facts, a finding of concealment can not be supported. The claims were incorrectly held invalid on this ground.

As a matter of law, we reverse the grant of partial summary judgment that claims 13, 14, 17, 18, 24-29, and 34 are invalid for failure to meet the best mode requirement. We remand with instructions that partial summary judgment be entered for Scripps on this ground.

V

Infringement

The district court found the R'011 product claims 24, 25, 28, and 29 literally infringed, explaining that "Human factor VII:C as claimed in the [product claims] therefore applies to any Factor VIII:C preparation, regardless of how produced, having the same material structural and functional characteristics as the plasma-derived preparation." The court did not distinguish between plasma-derived and recombinantly-produced human Factor VIII:C.[9] Genentech does not challenge this ruling as applied to plasma-derived VII:C.

A

Genentech appeals the district court's grant of Scripps' motion for summary judgment that the product claims are infringed by Genentech's recombinantly-produced human Factor VIII:C. Genentech states that the product claims should be construed, as a matter of law, to avoid infringement by recombinant VIII:C. Alternatively, Genentech argues that infringement is avoided by application of the reverse doctrine of equivalents. These two theories of non-infringement require different analytic approaches.

In "claim construction" the words of the claims are construed independent of the accused product, in light of the specification, the prosecution history, and the prior art. Of course the particular accused product (or process) is kept in mind, for it is efficient to focus on the construction of only the disputed elements or limitations of the claims. However, the construction of claims is simply a way of elaborating the normally terse claim language: in order to understand and explain, but not to change, the scope of the claims.

We described the workings of claim construction in *Tandon Corp. v. Int'l Trade Comm.*, 831 F.2d 1017, 1021, 4 USPQ2d 1283, 1286 (Fed. Cir. 1987):

> Claim interpretation is a question of law, having factual underpinnings. When the meaning of key terms of claims is disputed ... extrinsic evidence may be adduced including testimony of witnesses, and reference may be had to the specification, the prosecution history, prior art, and other claims.

Genentech argues that the term "a human VIII:C preparation" in the R'011 product claims should be construed as limited to the Factor VIII:C obtained by separation from plasma. In essence, Genentech argues that these claims should be construed as carrying an inherent process limitation, on the basis that Scrips did not invent human Factor VIII:C, or discover its structure, or its properties as the coagulant factor in blood, but simply the process of purifying it to a higher degree of purity than was heretofore available. However, Genentech also states that it is not challenging the propriety of product claims to Factor VIII:C; and it did not do so before the district court. While judicial attention has on occasion focused on the patentability of claims in this context, *see, e.g., In re Bergstrom*, 427 F.2d 1394, 166 USPQ 256 (CCPA 1970), Genentech, by conceding that the product claims were appropriately granted, presents inconsistent legal arguments. Genentech has not supported, as a matter of law, its requested claim construction.

B

The so-called "reverse doctrine of equivalents" is an equitable doctrine invoked in applying properly construed claims to an accused device. Just as the purpose of the "doctrine of equivalents" is to prevent "pirating" of the patentee's invention, *Graver Tank & Mfg. Co. v. Linde Air Prod. Co.*, 339 U.S. 605, 607, 608, 85 USPQ 328, 330, *reh'g denied*, 340 U.S. 845 (1950), so the purpose of the "reverse" doctrine is to prevent unwarranted extension of the claims

[9] In accordance with the recombinant procedure, the human Factor VIII:C gene is identified isolated and inserted int a host cell where it is replicated and from which Factor VIII:C is expressed and excreted into a culture medium. From this medium it is further purified using *inter alia* monocl nal antibodies to Factor VIII.C.

beyond a fair scope of the patentee's invention.

The reverse doctrine of equivalents flows from the Supreme Court's statement in *Graver Tank* that an accused article may avoid infringement, even if it is within the literal words of the claim, if it is "so far changed in principle from a patented article that it performs the same or a similar function in a substantially different way." 339 U.S. at 608-09, 85 USPQ at 330. Application of the doctrine requires that facts specific to the accused device be determined and weighed against the equitable scope of the claims, which in turn is determined in light of the specification, the prosecution history, and the prior art.

The record contained evidence of the properties of plasma-derived and recombinantly produced VIII:C, which was presented primarily by Scripps in connection with its proofs of infringement. There was deposition testimony that there were differences between VIII:C from plasma and VIII:C obtained by recombinant techniques; a Scripps' witness described the products as "apples and oranges", referring specifically to stability and formulations. The parties disputed, in connection with the summary judgment motions, the capabilities of the respective processes in terms of the purity and specific activities that were enabled for the respective products. The record on this point is extensive.

Genentech argues that its product is equitably seen as changed "in principle", particularly when viewed in the context of the prior art. Genentech asserts that the specific activities and purity that are obtainable by recombinant technology exceed those available by the Scripps process; an assertion disputed by Scripps, but which if found to be correct could provide — depending on the specific facts of similarities and differences — sufficient ground for invoking the reverse doctrine. These aspects were not discussed by the district court.

[10] The principles of patent law must be applied in accordance with the statutory purpose, and the issues raised by new technologies require considered analysis. Genentech has raised questions of scientific and evidentiary fact that are material to the issue of infringement. Consideration of extrinsic evidence is required, and summary judgment is inappropriate. *See. C.R. Bard, Inc. v. Advanced Cardiovascular Systems, Inc.*, 911 F.2d 670, 673, 15 USPQ2d 1540, 1542 (Fed. Cir. 1990).

The grant of summary judgment of infringement of claims 24, 25, 28, and 29 is reversed. The issue requires trial.

VI

Inducement to Infringe

The district court held that Genentech induced Cutter Laboratories to infringe claims 24, 25, 28, and 29 of the R'011 patent, 35 U.S.C. §271(b), through the use of both plasma-derived and recombinant Factor VIII:C. The court held:

> There is no question that Genentech delivered to Cutter materials found to have infringed, including recombinant and plasma-derived human Factor VIII:C, with the intent that Cutter itself would [develop recombinant Factor VIII:C]. . . . There is also no doubt that Genentech intended Cutter to use plasma-derived Factor VIII:C manufactured by both Genentech and Cutter which has been found to infringe.

Scripps, 666 F.Supp. at 1394, 3 USPQ2d at 1493. The facts of the relationship between Genentech and Cutter were undisputed.

Genentech states that the district court made no specific finding of direct infringement by Cutter, a predicate to a finding of inducement to infringe. Cutter is a division of Miles, a defendant herein, and is subject to the district court's finding of infringement. Thus the court's ruling on inducement was correct, as a matter of law. Subject to our holding in Part v, the decision of the district court on this issue is affirmed.

VII

Inequitable Conduct based on the Meyer Abstract

Genentech appeals the district court's grant of summary judgment that Scripps did not engage in inequitable conduct, during examination of the application that led to the '509 patent, based on a reference authored by Meyer, Obert, Zimmerman, and Edgington entitled *Monoclonal Antibodies Specific for Factor VIII from Cellular Hybrids*, No. 395 ("the Meyer abstract").

The district court observed that the Meyer abstract was cumulative to the complete Meyer paper it summarized:

> The Meyer abstract was also cited in a paper authored, *inter alia*, by Dr. Meyer herself that was submitted by Scripps to the PTO as reference RS. . . . In contrast to the Meyer abstract, which is only one paragraph long, reference RS is 27 pages in length and much more elaborate in its disclosure. . . .

Scripps, 666 F.Supp. at 1399-1400, 3 USPQ2d at 1496. A reference that is simply

cumulative to other references does not meet the threshold of materiality that is predicate to a holding of inequitable conduct. *Halliburton Co. v. Schlumberger Technology Corp.*, No. 90-1191, slip op. at 9 [17 USPQ2d 1834] (Fed. Cir. Feb. 15, 1991).

[11] The Meyer abstract was before the patent examiner who, according to Genentech, discovered it "on his own". When a reference has been considered by the examiner, it is not controlling how it came to the examiner's attention. The complete Meyer paper, and several other references, cited the Meyer abstract. Genentech argues that Scripps should nonetheless have brought the Meyer abstract to the examiner's specific attention, in addition to having listed the complete Meyer paper in Scripps' prior art statement. When a reference was before the examiner, whether through the examiner's search or the applicant's disclosure, it can not be deemed to have been withheld from the examiner.

Genentech presses the argument that the district court erred because the Meyer abstract was a "statutory bar", by which Genentech explains that it was published more than a year before the patent's filing date. Genentech does not explain how this was error, for the district court, like the PTO, treated as prior art both the 27-page Meyer paper and the Meyer abstract. Genentech's argument that the full paper "was not effective prior art" is contrary to law and fact, for it was published before the filing date of Scripps' '509 patent application and Scripps did not attempt to antedate the Meyer paper. It is thus immaterial when the Meyer abstract was published.

[12] Genentech also charged Scripps with inequitable conduct because Scripps originally sought claims to its monoclonal antibodies to Factor VIII:RP, and cancelled these claims after the examiner required Scripps to provide comparative data with the monoclonal antibodies described in the Meyer abstract and other references. While Genentech argues that obtaining such data was not the burden that Scripps said it was, this is irrelevant to the issue of inequitable conduct. An applicant has the absolute right to decline to do work suggested by the PTO, and to withdraw claims that had been presented for examination, without incurring liability for inequitable conduct.

The district court reviewed the Meyer abstract's content and found, without challenge on this appeal, that:

> [T]he Meyer et al. abstract contains no disclosure of the purification of Factor VIII:C. The Meyer et al. abstract contains no disclosure indicating that any of the monoclonal antibodies could be bound to substrate particles to form an immuno-a[d]sorbent for isolation and purification of VIII:C from the VIII:C/VIII:RP complex.
>
> The court concluded:
>
> Lacking such disclosure, the Meyer et al. abstract does not appear material to the examination of the claims that were presented in applicants' original application and issued in Patent No. 4,361,509.

Scripps, 666 F.Supp. at 1398, 3 USPQ2d at 1495. No error is ascribed to this conclusion. A reference that is material only to withdrawn claims can not be the basis of a holding of inequitable conduct. *Kimberly-Clark Corp. v. Johnson & Johnson Co.*, 745 F.2d 1437, 1457, 223 USPQ 603, 616-17 (Fed. Cir. 1984).

The party with the burden of proof of inequitable conduct must meet the clear and convincing standard. *FMC Corp. v. Manitowoc Co.*, 835 F.2d 1411, 1417 n.11., 5 USPQ2d 1112, 1117 n.11 (Fed. Cir. 1987). Genentech did not offer evidence or legal argument whereby, even drawing all factual inferences in its favor, this standard could be met at trial, as to either materiality of the Meyer abstract, or intent to deceive or mislead. The district court's grant of partial summary judgment of no inequitable conduct based on the Meyer abstract is affirmed.

VIII

Infringement of the Product-by-Process Claims

Scripps appeals the district court's refusal to grant its motion for summary judgment of infringement of the R'011 product-by-process claims 13, 14, 17, 18, and 34. The district court denied Scripps' motion under Rule 59(e) to amend the judgment to rule on this question. Genentech argues that this denial is not appealable, and has moved for dismissal. Looking to the law of the Ninth Circuit, an appeal from a final judgment may include challenges to "all rulings which produced the judgment". *Munoz v. Small Business Administration*, 644 F.2d 1361, 1364 (9th Cir. 1981). *See Moran v. Aetna Life Insurance Co.*, 872 F.2d 296, 301 (9th Cir. 1989) (denial of a summary judgment motion is appealable after entry of final judgment); 10 C. Wright, A. Miller, and M. Kane, *Federal Practice & Procedure* §2715 (2d ed. 1983). The issue is reviewable, but on an undeveloped record we consider only the questions of law.

[13] Scripps charges that Genentech's recombinantly-produced Factor VIII:C infringes the product-by-process claims, either literally or by application of the doctrine of equivalents. The district court remarked that the product-by-process claims would not be infringed unless the same process were practiced. Scripps correctly points out that this statement appears to diverge from our precedent, recognizing that this precedent arose in the context of patent prosecution, not patent infringement. *E.g., In re Thorpe,* 777 F.2d 695, 227 USPQ 964 (Fed. Cir. 1985) (holding that prior art pertinent only to product is proper ground for rejecting product-by-process claims); *In re Brown,* 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972) (in product-by-process claims the patentability of the product must be established independent of the process); *In re Bridgeford,* 357 F.2d 679, 682 n.5, 149 USPQ 55, 58 n.5 (CCPA 1966) (recognizing that some courts in infringement litigation have construed product-by-process claims as limited to the particular process, but holding that patentability is determined independent of the process). In determining patentability we construe the product as not limited by the process stated in the claims. Since claims must be construed the same way for validity and for infringement, the correct reading of product-by-process claims is that they are not limited to product prepared by the process set forth in the claims. Thus, these claims are subject to an infringement analysis similar to that described in Part V, *ante.* Infringement of the product-by-process claims may be considered at trial.

IX

Attorney Fees

The district court held that this was an exceptional case under 35 U.S.C. §285, apparently due to the court's rulings on inequitable conduct and failure to comply with the best mode. Holdings under §285 are reviewed for abuse of the trial court's discretionary authority, considering the court's findings and conclusions and any other appropriate factors. *See Reactive Metals & Alloys Corp. v. ESM, Inc.,* 769 F.2d 1578, 1583, 226 USPQ 821, 824 (Fed. Cir. 1985). In view of our reversal of the grants of summary judgment on the issues of best mode and inequitable conduct, the award of attorney fees flowing therefrom must be vacated. *See State Indus., Inc. v. A.O. Smith Corp.,* 751 F.2d 1226, 1238, 224 USPQ 418, 426 (Fed. Cir. 1985) (reversing ground for holding case exceptional and accompanying award of attorney fees).

X

Other Issues

We have not repeated all the arguments and issues raised by both sides, including charges of frivolity, misstatement, and worse. Encumbered by the summary nature of the proceedings, neither scientific nor evidentiary truth has risen easily to the surface. However, we *DENY* Scripps motion for sanctions against Genentech for filing a frivolous cross-appeal, for some of the issues raised were not clearly hopeless in law and fact. We also *DENY* each side's motions to strike various materials filed and to dismiss issues raised by the other.

Costs

Each party shall bear its costs.

AFFIRMED IN PART, REVERSED IN PART, VACATED IN PART, AND REMANDED

Court of Appeals, Federal Circuit

Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.

Nos. 90-1273, -1275

Decided March 5, 1991

PATENTS

1. Patentability/Validity — Date of invention — Conception (§115.0403)

Conception of chemical compound requires that inventor be able to define compound so as to distinguish it from other materials, and to describe how to obtain it, rather than simply defining it solely by its principal biological property; thus, when inventor of gene, which is chemical compound albeit complex one, is unable to envision detailed constitution of gene so as to distinguish it from other materials, as well as method for obtaining it, conception is not achieved until reduction to practice has occurred, and until after gene has been isolated.

2. Patentability/Validity — Date f invention — Conception (§115.0403)

Conception of generalized approach for screening DNA library that might be used to

In re Wilder et al.

Court of Appeals, Federal Circuit

No. 83-1360

Decided June 20, 1984

United States Patents Quarterly Headnotes

PATENTS
[1] Reissue -- In general (§ 58.1)
Reissue oath or declaration must state that patent is defective or partly inoperative or invalid because of defects in specification or drawing, or because patentee has claimed more or less than he is entitled to; second, applicant must allege that defective, inoperative, or invalid patent arose through error without deceptive intent.

PATENTS
[2] Reissue -- In general (§ 58.1)
Error provision of 35 USC 251 is to be liberally construed to permit correction of defects; attorney's failure to appreciate full scope of invention is one of most common sources of defects in patents; fact that error could have been discovered at time of prosecution with more thorough patentability search or with improved communication between inventors and attorney does not, by itself, preclude patent owner from correcting defects through reissue; where attorney's error was discovered after commercialization of invention and issuance of patent, and where application for broader claims was filed within two years after original patent issued, attorney's explanation of his error in misunderstanding scope of invention is sufficient to satisfy error requirement of 35 USC 251.

PATENTS
[3] Reissue -- In general (§ 58.1)
Attorney's declaration that his error, misunderstanding scope of invention, arose because no prior art search was done and he assumed limitations were required by prior art, without justification, is sufficient explanation of how error arose to satisfy requirements of 37 CFR 175(a)(5).

PATENTS
[4] Specification -- Sufficiency of disclosure (§ 62.7)
Description requirement of 35 USC 112 is separate from enablement requirement of that provision; it is not necessary that claimed subject matter be described identically, but that disclosure originally filed convey to those skilled in art that applicant had invented subject matter later claimed; precisely how close original description must come to comply with description requirement of Section 112 must be determined on case by case basis; inquiry into whether description requirement is met is question of fact.

PATENTS
[5] Construction of specification and claims -- Broad or narrow (§ 22.101)
Subjective desire to claim as broadly as possible does not establish that broader invention being claimed in reissue application is adequately described in original patent.

PATENTS
[6] Reissue -- In general (§ 58.1)
Objects of the Invention may, in some cases, provide support for claims sought through reissue.

PATENTS
Particular patents -- Tape Scanning Devices
Wilder, Whitney, and Matison, Instruction Indicating Apparatus for a Record and/or Playback Device, rejection of claims 1-16 reversed; rejection of claims 14-16 affirmed.

***369** Appeal from Patent and Trademark Office Board of Appeals.

Application for reissue of patent of Leslie N. Wilder, James C. Whitney, and Gary G. Matison, Serial No. 079,171 filed to reissue Patent No. 4,051,540. From decision rejecting claims 1-16, applicants appeal (Lanier Business Products intervenor). Affirmed in part and reversed in part.

Gregor N. Neff, New York, N.Y. (William S. Frommer, New York, N.Y., and Melvin J. Scolnick, Stamford, Conn., of counsel) for appellants.

Thomas E. Lynch (Joseph F. Nakamura, and Jere W. Sears, on the brief) for Patent and Trademark Office.

Eugene S. Zimmer, Atlanta, Ga., for intervenor.

Before Baldwin, and Kashiwa, Circuit Judges, and

Nichols, Senior Circuit Judge.

Baldwin, Circuit Judge.

This appeal is from a decision of the United States Patent and Trademark Office Board of Appeals (board) rejecting claims 1-16 of appellant's Reissue Application Serial No. 079,171. Claims 1-16 were rejected for appellants' failure to sufficiently allege error required by 35 USC §251 and for failure of appellants' oath to meet the requirements of 37 CFR 1.175(a)(5). Claims 14-16 were also rejected as being drawn to subject matter not disclosed in the original patent, U.S. Patent ***370**(Cite as: 222 U.S.P.Q. 369, *370) No. 4,051,540. We reverse the board's rejection of claims 1-16 for failure properly to allege error as required by the statute and regulation but affirm the board's rejection of claims 14-16 on the ground that the disclosure requirement has not been satisfied.

The Invention

The invention claimed in U.S. Patent No. 4,051,540 (the original patent) is a mechanism for indicating the location of information recorded on a dictating machine. A person speaking into a dictating machine indicates the location of instructions on a recording medium, such as a magnetic tape, by recording control tones at the beginning or end of the instructions. A person transcribing dictated information rewinds the tape in a transcribing machine. During rewinding, the transcribing machine scans the tape and detects control tones. The locations of detected tones are stored in an electrical circuit and lights appear on a linear array that correlate with the locations of control tones on the tape. After rewinding, the transcriptionist locates specific information by advancing the tape until an indicator aligns with a light in the array.

Claim 1 of the original patent is reproduced below:

> 1. Apparatus for indicating the location of particular information on a previously recorded record medium, said particular information being represented by predetermined recorded signals, comprising:
>
> scanning means for scanning said record medium;
>
> an array of selectively actuable light emitting sources;
>
> indexing means for scanning said array of light emitting sources in synchronism with the scanning of said record medium, said indexing means being in actuating relation sequentially with each of said light emitting sources;
>
> detecting means for detecting the presence of said predetermined recorded signals during the scanning of said record medium to produce an actuating signal; and
>
> temporary storage means for temporarily storing said actuating signal until said indexing means is in actuating relation with an unenergized light emitting source to energize said light emitting source. [Emphasis added.]

Claims 1-13 of the Reissue application are the same as claims 1-13 of the original patent. Unlike the original claims, reissue claims 14, 15, and 16 do not require that lights be scanned "in synchronism with the scanning of said record medium." Accordingly, the original claims are directed to a species while the reissue claims are directed to the genus of indicating mechanisms that visually identify positions on a recording medium when the recording medium is scanned.

Opinion

Error Rejections

The first order of business for the board and for this court is to determine whether appellants have satisfied the requirements of 35 USC §251 and 37 CFR 1.175. In re Clark, 522 F.2d 623, 625, 187 USPQ 209, 211 (CCPA 1975); In re Rowand, 526 F.2d 558, 559, 187 USPQ 487, 488 (CCPA 1975).

[1] The statute, 35 USC §251, provides, in pertinent part, that:

> Whenever any patent is, through error without any deceptive intention, deemed wholly or partly inoperative or invalid, by reason of a defective specification or drawing, or by reason of the patentee claiming more or less than he had a right to claim in the patent, the Commissioner shall, on the surrender of such patent and the payment of the fee required by law, reissue the patent for the invention disclosed in the original patent, and in accordance with a new and amended application,

> for the unexpired part of the term of the original patent. No new matter shall be introduced into the application for reissue.

There are two distinct statutory requirements that a reissue oath or declaration must satisfy. First, it must state that the patent is defective or partly inoperative or invalid because of defects in the specification or drawing, or because the patentee has claimed more or less than he is entitled to. Second, the applicant must allege that the defective, inoperative, or invalid patent arose through error without deceptive intent. The applicants satisfied the first requirement by alleging less was claimed in the original patent than the patentee was entitled to claim. The only issue is whether error correctable through reissue was properly alleged.

The error alleged in the first declaration filed by the inventors was that:

> [t]he true scope of the invention disclosed in the patent was not fully appreciated by us or by our attorney * * * until the commercial success of the "Thought Master" record/playback device was found to be based, at least in part, on the linear array of fixed, selectively energizable light elements, each being selectively energized to ***371** provide a visual light mark in response to a detected predetermined signal, and each being associated with a respective length of record tape, which is provided in the electronic indicator incorporated in the said "Thought Master" record/playback device * * *.

The attorney who prosecuted the original patent stated in a declaration accompanying the reissue application:

> 3. That I did not fully appreciate the true nature and scope of the invention disclosed in the original application and thus did not prepare claims of broad enough scope to provide the patent protection to which the invention properly is entitled.
>
> 6. My failure to fully appreciate the true nature and scope of the invention disclosed in the original application was without fraudulent or deceptive intention, and arose from inadvertence, accident or mistake.

In a subsequent declaration, the attorney further elaborated on the cause of his error with the following explanations:

> 7. The invention disclosed in said original application was incorporated into a dictating machine sold by the assignee of said patent under the trademark "Thought Master." When said patent issued, sales of this device had only recently begun. Subsequently, in the latter half of 1978, said assignee began marketing a modified version of a dictating machine, identified as the "Thought Master II" machine. Differences between these versions of the Thought Master dictating machines are described below.
>
> 8. In the summer of 1979, I conferred with James C. Whitney, the only one of the inventors still employed by the assignee, regarding the question of the scope of protection secured by said patent. Particularly, Mr. Whitney requested that I investigate the scope of said patent to determine if it adequately covered both versions of the Thought Master machine, and also if said patent adequately protected the broad invention disclosed therein from what Mr. Whitney believed to be possible attempts by competitors of the assignee who, in the future, might try to exploit said invention.
>
> 9. In accordance with Mr. Whitney's request, I investigated the claims of said patent in light of the prior art of which I then was aware. From my investigation, I concluded that said patent could support broader claims whose scope, broadly, is the combination of a linear array of fixed, selectively energizable light elements, each being selectively energized from an inactive condition to an active condition to provide a visual light mark representing its active condition, a detector for detecting a predetermined signal as the record tape, upon which the predetermined signal is recorded, is being scanned to produce an actuating signal, a storage device for storing the actuating signal and an energizing circuit for energizing a respective light element, commensurate with the location of the record tape being scanned, with the stored actuating signal so as to provide, upon scanning the record tape, a display of the relative locations of the predetermined signals on the record tape. I further concluded that the limitations in the broadcast claim of said patent, quoted above in paragraph 5, is [sic] not essential for practicing

> the broad teachings of the invention disclosed in said patent, and I advised Mr. Whitney that, because of this limitation, the scope of the patent was not adequate to protect the invention properly.
>
> 10. I recognized, when I investigated the claims of said patent, that my speculation of the prior art, as hereinabove stated, was unwarranted and erroneous.

These statements in the declarations accompanying the reissue application show that the error relied upon is the attorney's failure to appreciate the full scope of the invention. That error arose because the attorney assumed the presence of features in the prior art that were not there. The board concluded this is not error that may be corrected through reissue because the defect could have been discovered during prosecution of the original patent. The board said. "[t]here may have been a lack of prescience of the existence of a genus but such lack of prescience does not constitute an error in the sense of section 251."

[2] The error provision of 35 USC §251 is to be liberally construed to permit correction of defects. Ball Corp. v. United States, 729 F.2d 1429, 1436, 221 USPQ 289, 294 (Fed. Cir. 1984); In re Oda, 443 F.2d 1200, 1203, 170 USPQ 268, 270 (CCPA 1971). An attorney's failure to appreciate the full scope of the invention is one of the most common sources of defects in patents. The fact that the error could have been discovered at the time of prosecution with a more thorough patentability search or with improved communication between the inventors and the attorney does not, by itself, preclude a patent owner from correcting defects through reissue. In this case, the attorney's error was discovered after commercialization of the invention and issuance of the patent. An application for broader ***372** claims was filed within two years after the original patent issued. Under these circumstances, the attorney's explanation of his error in misunderstanding the scope of the invention is sufficient to satisfy the error requirement of 35 USC §251. We accordingly reverse the board's rejection for failure to allege error correctable through reissue.

[3] The examiner also rejected appellants' application for failure to comply with the requirements of 37 CFR §1.175(a)(5). The board affirmed this rejection without comment. The regulation relied on by the examiner and the board requires:

> 1.175 Reissue oath or declaration
> (a) Applicants for reissue * * * must also file with their applications a statement under oath or declaration as follows:
>
> (5) Particularly specifying the errors relied upon, and how they arose or occurred.

The examiner found that applicants failed to allege facts that explain how the error arose. This finding is clearly erroneous. In re De Blauwe, Appeal No. 84-513, slip op. at 10, 222 USPQ 191 (Fed. Cir. June 8, 1984). The attorney who prosecuted the patent declared that his error, misunderstanding the scope of the invention, arose because no prior art search was done and he assumed limitations were required by the prior art without justification. This, in our view, is a sufficient explanation of how the error arose to satisfy the requirements of 37 CFR §1.175(a)(5).

Disclosure Rejection Of Claims 14-16

[4] The board rejected claims 14-16 for inadequate description to support generic claims that do not require synchronous scanning. The description requirement is found in 35 USC §112 and is separate from the enablement requirement of that provision. In re Bowen, 492 F.2d 859, 864, 181 USPQ 48, 52 (CCPA 1974); In re Smith, 481 F.2d 910, 914-15, 178 USPQ 620, 623-25 (CCPA 1973). It is not necessary that the claimed subject matter be described identically, but the disclosure originally filed must convey to those skilled in the art that applicant had invented the subject matter later claimed. In re Kaslow, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed.Cir. 1983). Precisely how close the original description must come to comply with the description requirement of section 112 must be determined on a case by case basis. In re Smith, 458 F.2d 1389, 1395, 173 USPQ 679, 683 (CCPA 1972). We fail to see that the board's finding of inadequate description [FNa1] is clearly erroneous. In re De Blauwe, Appeal No. 84-513, slip op. at 10, 222 USPQ 191 (Fed. Cir. June 8, 1984), and accordingly affirm the board's rejection of claims 14-16.

[5] Appellants admit that the synchronous scanning equipment is the only embodiment of the invention disclosed in the original patent. To overcome the board's decision, appellants' point out that the

description of one of the drawings says that dictation apparatus illustrated in the drawing is "one in which the present invention finds ready application." Appellants also note that the title of the patent "Instruction Indicating Apparatus For A Record And/Or Playback Device" is quite broad. The general description of a drawing and the broadly phrased title of the patent demonstrate, appellants contend, that other embodiments are contemplated and are sufficient to satisfy the disclosure requirement. These phrases relied upon by appellants demonstrate a desire to claim the invention as broadly as the prior art would allow. But a desire to claim as broadly as possible is the objective of most applicants for a patent. This subjective desire does not establish that the broader invention being claimed in this reissue application is adequately described in the original patent. The broadly worded title of the original patent and customarily broad description of the drawing do not satisfy the description requirement in this case.

[6] Appellants also rely on statements in the Objects of the Invention section of the specification to satisfy the description requirement. The Objects of the Invention may, in some cases, provide support for claims sought through reissue. In re Handel, 312 F.2d 943, 136 USPQ 460 (CCPA 1963). They do not satisfy the disclosure requirement in this case. For instance, one of the recited objects says:

> [I]t is an object of the present invention to provide improved indicating apparatus for indicating the location of particular information on a record medium which overcomes the aforenoted problems.

The "aforenoted problems" relate to difficulties associated with paper scales graduated in minutes previously used to note the approximate place on a tape where instructions were located. In our view the board correctly read the Objects of the Invention as doing little more than outlining goals appellants hope the *373 claimed invention achieves and the problems the invention will hopefully ameliorate. But the invention that achieves these general objectives must still be described. Appellants have not shown that the generic invention of claims 14-16 is supported by the original patent's disclosure in such a way as would indicate possession, as of the original filing date, of that generic invention. The present situation is to be distinguished from this court's recent decision in In re Peters, 723 F.2d 891, 221 USPQ 952 (Fed.Cir. 1983) , brought to our attention by appellants. In Peters, the appellant successfully rebutted the PTO's rejection by proving that the broadened claims "merely omit an unnecessary limitation [the word "tapered"] that had restricted one element of the invention to the exact and non-critical shape disclosed in the original patent." Id. at 893, 221 USPQ at 953. The court further commented: "Indeed, if the reissue claims had been submitted with the original application, it is difficult to perceive how they could have been properly rejected under §112." Id. at 894, 221 USPQ at 953.

For the foregoing reasons, we reverse the board's rejection of claims 1-16 for failure to allege error correctable through reissue and the cause of the error. We affirm the board's rejection of claims 14-16 for claiming subject matter not adequately disclosed in the original patent.

Reversed in Part and Affirmed in Part

FNa1 The inquiry into whether the description requirement is met is a question of fact. In re Wertheim, 541 F.2d 257, 262, 191 USPQ 90, 96 (CCPA 1976); In re Ruschig, 379 F.2d 990, 996, 154 USPQ 118, 123 (CCPA 1967).

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222 U.S.P.Q. 369

END OF DOCUMENT

[2] As to the final prong of the "governmental interest" test, the court finds that California law will be greatly impaired if New York law is applied to this dispute. Despite the fact that this dispute can be traced to the employment relationship between Page and Klaw in New York some 40 years ago, the court must still focus on the time period when the alleged injury took place. As the Ninth Circuit has explained in the context of a defamation case:

> Each [state] has an interest in having its laws applied, due primarily to the fact that residents of each are parties to this action. . . . Without question, the district court was correct in concluding that in this case California's interest would be more impaired if its laws were not applied. New York is indeed the state in which the defendants both reside and in which the allegedly defamatory remarks were uttered. However, because California is the state in which both plaintiffs lived and worked throughout the transactions involved, it is the state where the damage to plaintiffs' reputations, if any, would have occurred. As the district court noted, New York has "absolutely no interest in the reputation of a California citizen." The fact that California is the forum state further strengthens our conclusion, for we have said that in cases of this nature application of the laws of the forum state is preferred.

Yagman, 796 F.2d at 1170-1171.

Here, it is undisputed that Page has been a California resident since the time that the derivative works were copyrighted and the "new" art work was created. Further, it appears that in 1993, when the defendants created the "new" art work which was used to advertise the videos, none of the parties to this dispute had any connections to New York. Under these circumstances, the "governmental interest" test requires that California law be applied to this dispute. *See Gifford v. National Enguirer, Inc.*, 1993 WL 767192, * *1-2 (C.D. Cal. December 7, 1993).

CONCLUSION

As set forth above, the court concludes that California law governs this dispute. Plaintiffs shall have 30 days from service of this order to file their motions for summary judgment.

IT IS SO ORDERED.

U.S. Court of Appeals Federal Circuit

In re Swartzel

No. 94-1482

Decided June 28, 1995
(Unpublished)

PATENTS

1. Practice and procedure in Patent and Trademark Office — Reissue — Error without deceptive intent (§110.1303)

Applicant who responds to restriction requirement from Patent and Trademark Office by canceling claims to non-elected invention, and who fails to file divisional application with canceled claims, is deemed to have acquiesced to restriction and is estopped from obtaining subject matter of canceled claims by reissue; this "divisional doctrine" is strictly construed against reissue applicants claiming "error" in failing to file divisional application after restriction requirement but will not be extended as mechanical rule against reissue in which PTO's actions are only "tantamount" to restriction requirement.

2. Practice and procedure in Patent and Trademark Office — Reissue — Error without deceptive intent (§110.1303)

Reissue claims for method of ultrapasteurizing liquid whole egg product were improperly rejected on ground that applicant intentionally forfeited claims in question by failing to file divisional application after entry of amendment was refused during prosecution of original application, since applicant's declaration establishes that he misunderstood scope of product by process claims filed in original application, and since applicant would not have filed attempted amendment on which reissue rejection was based had he known proper scope of claims.

Particular patents — Chemical — Liquid egg product

5,019,408, Swartzel, Ball and Hamid-Samimi, method for the unltrapasteurization of liquid whole egg products, rejection of claims 1-19, 28-35, 46 and 47 in application for reissue reversed.

Appeal from the U.S. Patent and Trademark Office, Board of Patent Appeals and Interferences.

Application of Kenneth R. Swartzel, Hershell R. Ball and Mohammed-Hossein Hamid-Samimi, serial no. 07/880,899, for reissue of patent no. 5,019,408. From decision upholding final rejection of claims, applicants appeal. Reversed.

[Editor's Note: The U.S. Court of Appeals for the Federal Circuit has indicated that, "[p]ursuant to Fed.Cir.R. 47.6, this disposition is not citable as precedent. It is a public record."]

Before Archer, chief judge, and Clevenger and Schall, circuit judges.

Archer, C.J.

DECISION

Kenneth R. Swartzel, *et al.* (collectively Swartzel) appeal from the July 28, 1994 decision of the Patent and Trademark Office (PTO) Board of Patent Appeals and Interferences (board) affirming a final rejection of claims 1-19, 28-35, 46 and 47 of Swartzel's application serial no. 07/880,899 for reissue of U.S. patent no. 5,019,408. We *reverse*.

DISCUSSION

I

The '408 patent has claims directed to a method of ultrapasteurizing a liquid whole egg product. The '899 reissue application seeks to add product and product by process claims directed to the liquid whole egg product to the '408 patent. The board affirmed the examiner's final rejection of the product and product by process claims under 35 U.S.C. § 251 as lacking statutory basis for failure to state "error" capable of being remedied under § 251. Specifically, the board affirmed the examiner's finding that Swartzel had surrendered the opportunity to obtain product claims when he failed to file a divisional application from the '408 patent's grandparent application in response to an examiner's refusal to enter a proposed amendment containing product by process claims.

The '408 patent was issued from application serial no. 628,716, which was a continuation of application serial no. 535,718, which was a continuation of application serial no. 311,594, which was a continuation of application serial no. 904,744. All of these applications issued as separate patents covering methods of ultrapasteurizing liquid whole egg products. During the prosecution of the '594 application, Swartzel attempted to file an amendment in response to an office action that canceled all the pending method claims and substituted product by process claims. The examiner refused to enter the amendment on the grounds that "the [proposed] claims are not readable on the elected [by original presentation] invention because the egg product instantly claimed could be made by a process other than the one recited." In response, Swartzel filed a second amendment amending the method claims.

The board rejected Swartzel's product and product by process claims in the '408 patent reissue proceeding based on this evidence. The board concluded that the examiner's refusal to enter the product by process claims in the '594 application was "tantamount" to a restriction requirement and that by not filing a divisional application, Swartzel had intentionally surrendered product by process claims. Subject matter that has been intentionally surrendered cannot be recovered under § 251 because there has been no "error." *In re Weiler*, 790 F.2d 1576, 1582, 229 USPQ 673, 677 (Fed. Cir. 1986). The board further reasoned that because product by process claims are examined as product claims, product claims were also surrendered.

Swartzel contends that product claims were never surrendered and thus *Weiler* does not apply. The reissue declaration (as amended) of the '899 application essentially recites two types of "error" made without deceptive intent that resulted in Swartzel claiming less than he had a right to in the '408 patent. First, Swartzel contends he reasonably believed, incorrectly, that others had successfully made the liquid whole egg product before him and thus he was not entitled to product claims. Second, Swartzel (and his attorney) admits he did not understand how the PTO interprets product by process claims when he attempted to file the unentered amendment in the '594 application. On appeal, Swartzel argues that when he was informed by the examiner that the PTO treats product by process claims as product claims, without regard to process limitations, he did not believed a divisional application could be filed because of his erroneous factual belief that others had created the product first. Swartzel further avers that when he learned that his information had been wrong and that no one else had been successful in creating the product disclosed in the '408 patent, he promptly filed the '899 reissue application.

II

[1] Where the PTO issues a restriction requirement and the applicant responds by canceling claims to the nonelected invention, and then the applicant fails to file a divisional application with the canceled claims, applicant is deemed to have acquiesced to the restriction and is estopped from obtaining by reissue the subject matter of the canceled claims. *In re Orita*, 550 F.2d 1277, 1280, 193 USPQ 145, 148 (CCPA 1977). This "divisional doctrine" has been strictly construed against reissue applicants claiming "error" in failing to file a divisional application after a restriction requirement. Even if the applicant's representative misunderstood the applicant's instructions, this does not constitute "error" within the meaning of § 251. *See Weiler*, 790 F.2d at 1582, 229 USPQ at 677. "Section 251 is not a panacea designed to cure every mistake which might be committed by an applicant or his attorney." *Orita*, 550 F.2d at 1281, 193 USPQ at 149.

On the other hand, § 251 is a remedial statute that is to be interpreted liberally. *Weiler*, 790 F.2d at 1579, 229 USPQ at 675. "Although attorney error is not an open invitation to reissue every case in which it may appear . . . the purpose of the reissue statute is to avoid forfeiture of substantive rights due to error made without intent to deceive." *Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565, 1575, 18 USPQ2d 1001, 1009 (Fed. Cir. 1991) (cites omitted). Accordingly, we decline to extend any mechanical rule against reissue where the PTO's actions are only "tantamount" to a restriction requirement. *See* 37 C.F.R. § 1.145 (limiting restrictions to amendments that have been entered).

[2] Swartzel's declaration establishes that he (and his representative) misunderstood the scope of the product by process claims filed in the '594 application. "An attorney's failure to appreciate the full scope of the invention is one of the most common sources of defects in patents." *In re Wilder*, 736 F.2d 1516, 1519, 222 USPQ 369, 371 (Fed. Cir. 1984). Had Swartzel known the proper scope of the claims, the amendment would not have been filed because Swartzel did not believe he was entitled to claims of that scope. Thus Swartzel cannot be said to have intentionally forfeited claims covering the liquid whole egg product. He did not understand that to be the scope of the unentered claims when he filed them.

The board based its decision affirming the rejection of the claims solely on the events surrounding the prosecution of the '594 application, finding that Swartzel's failure to file a divisional after the examiner refused entry of his amendment precluded recapture of any subject matter in that amendment. Because we conclude that such a per se rule against reissue is inappropriate on these facts, and because we conclude Swartzel's declaration establishes "error without deceptive intention" correctable under 35 U.S.C. § 251, we reverse.[1]

[1] We decline to consider the alternative bases the Solicitor offers for affirming the Board's decision, noting that the board did not rely on these bases for rejection and that they were apparently abandoned by the examiner prior to the appeal to the board.

In re Weiler, et al.

Court of Appeals, Federal Circuit

No. 85-2085

Decided May 8, 1986

United States Patents Quarterly Headnotes

PATENTS
[1] Reissue -- Inadvertence, accident and mistake (§ 58.3)
PTO Appeal Board's finding that subject matter of claims in reissue application was not claimed in original application, and its finding that nothing in original patent evidences applicant's "intent to claim" that subject matter, supports its finding that such failure was not "error" intended to be corrected by reissue under 35 USC §251.

PATENTS
Particular Patents -- Chemical
Reissue application No. 408,497, Method for Quantitative Analysis for Limonin, rejection of claims 13 and 19 sustained.

***673** Appeal from Patent and Trademark Office Board of Patent Appeals and Interferences.

Reissue application, Serial No. 408,497, by Elmar W. Weiler and Richard L. Mansell. From decision sustaining rejection of claims 13 and 19, applicants appeal. Affirmed.

William D. Stokes, Alexandria, Va., for appellants.

Richard E. Schafer, Associate Solicitor, Arlington, Va. (Joseph F. Nakamura, Solicitor, and Fred E. McKelvey, Deputy Solicitor, on the brief) for appellee.

Before Markey, Chief Judge, Davis and Bissell, Circuit Judges.

Markey, Chief Judge.

Weiler and Mansell (Weiler) appeal from a decision of the United States Patent and Trademark Office Board of Appeals (board), App. No. 600-54 (Dec. 31, 1984), affirming the examiner's rejection of claims 13 and 19 in a reissue application filed under 35 U.S.C. §251 (1982). We affirm.

***674** Background

Weiler filed an application on May 8, 1980, containing 11 claims. During prosecution, the examiner held that the application contained "three independent and distinct inventions" and required restriction between Claims 1- 7 (assay method), Claims 8 and 11 (an "organic compound" in class 260/343.42), and Claims 9 and 10 (a "protein compound" in class 260/121). Weiler elected to prosecute Claims 1-7. Those claims were allowed without amendment, and the application issued on December 15, 1981 as U.S. Patent No. 4,305,923 ('923 patent) for a "Method for Quantitative Analysis for Limonin".

1. U.S. Patent No. 4,305,923

The seven claims of the patent are independent claim 1 and dependent claims 2-7. Claim 1 reads:

> 1. A method for quantitative analysis of limonin which comprises reacting a known amount of limonin-specific antibodies, with a mixture of a known volume of sample containing an unknown amount of limonin and a known amount of a limonin-derivative labeled with an enzyme or with a radioactive isotope, determining the amount of labeled limonin-derivative which has reacted with said antibodies and calculating therefrom the unknown amount of limonin in said sample.

2. The Reissue Application

Weiler did not contest the examiner's requirement for restriction and did not file a divisional application, to assert the non-elected claims or any other claims.

On August 18, 1982, Weiler filed application Serial No. 408,497 to reissue the '923 patent. In this Declaration, Weiler said the '923 patent was partly inoperative or invalid by reason of his having claimed less than he had a right to claim, and that that deficiency "exists because of errors which were made without deceptive intent on my part."

Weiler alleged "an extraordinary sequence of events which preceded and followed the inadvertent abandonment of original claims 8-11" which made

him aware that the invention of the '923 patent was not adequately claimed. His Declaration set forth: (1) a June 23, 1981 letter from patent attorney Earl Tyner to Manzell (co-inventor of the '923 invention) confirming Manzell's authorization to file a divisional application on claims 8-11; (2) Tyner's July 2, 1981 letter to Bryan Burgess (Office of General Counsel, University of Florida), about filing a divisional application; and (3) a January 19, 1982 letter to Mansell from Arthur Yeager, a partner in Tyner's firm, stating that a divisional application had not been filed.

The Declaration further stated that "on being made aware of the failure to timely file the divisional application," Mansell consulted with patent attorney William D. Stokes (counsel of record here), who drafted a set of claims which, he said in the Declaration, "should have been made in the original application."

3. The Reissue Claims

The reissue application contained 20 claims. Claim 13 reads:

> 13. A method for developing citrus fruit strains low in limonin content, which method comprises identifying by the use of limonin-specific antibodies as a analytical reagent the limonin-low mutants in a breeding or cell culture program, and propagating said mutants.

Claim 19 reads:

> 19. A gamma globulin fraction comprising antibodies reactive with limonin, said antibodies being formed consequent to injecting into an animal a limonin-protein conjugate.

Claims 1-12 and 20 were allowed by the examiner. Claim 2 was cancelled by Weiler. Claims 13-19 were rejected, and that rejection was appealed to the board.

4. The Board's Action

The board agreed with the examiner's view that "failure to timely file a divisional application including non-elected claims is a deliberate act and not error in the prosecution of the original patent" (citing in re Orita, 550 F.2d 1277, 193 USPQ 145 (CCPA 1977)). It sustained the rejection of claims 14-18 on that ground, i.e., because they are directed to the same subject matter as the non-elected conjugate claims 9 and 10 of the original application. Claims 14-18 are not before us on appeal.

The board sustained the rejection of claims 13 and 19 on this specific ground:

> Appeal claims 13 and 19 are directed to subject matter not claimed at all in the original application. As to them, the Examiner's reliance on the case of In re Rowand et al. is entirely correct and that decision is controlling. Here, as in that case, "there is nothing in the original patent evidencing that appellants intended to claim (this now claimed subject matter)" (187 USPQ 487 at 489).

Issue

Whether the board erred in sustaining the rejection of claims 13 and 19.

OPINION

Introduction

The starting place is the statute itself, 35 U.S.C. § 251.

> *675 Whenever any patent is, through error without any deceptive intention, deemed wholly or partly inoperative or invalid, by reason of a defective specification or drawing, or by reason of the patentee claiming more or less than he had a right to claim in the patent, the Commissioner shall, on surrender of such patent and the payment of the fee required by law, reissue the patent for the invention disclosed in the original patent, and in accordance with a new and amended application, for the unexpired part of the term of the original patent. No new matter shall be introduced into the application for reissue.

In enacting the statute, Congress provided a statutory basis for correction of "error". The statute is remedial in nature, based on fundamental principles of equity and fairness, and should be construed liberally. In re Bennett, 766 F.2d 524, 528, 226 USPQ 413, 416 (Fed. Cir. 1985) (in banc); Ball Corp. v. United States, 729 F.2d 1429, 1439 n.28, 221 USPQ 289, 296 n.28 (Fed. Cir. 1984); In re Hay, 534 F.2d 917, 919, 189 USPQ 790, 791 (CCPA 1976). Nonetheless, not every event or circumstance that might be labeled "error" is correctable by reissue.

A. The Parties' Contentions

Weiler says the subject matter of neither claim 13 nor claim 19 constitutes "an independent and distinct invention" from that secured by the original patent, because both subject matters constituted part of the invention which was intended or sought to be secured by the original patent.

Pointing to the letters about a divisional application, on other claims, Weiler says his failure to claim the subject matter of claims 13 and 19 was not deliberate or purposeful, but was caused by the prosecuting attorney's error. He says that "but for the inventors' ignorance of patent drafting technique, their lack of knowledge of claiming technique, and their attorney's obvious lack of understanding of the invention, the subject matter of the part of the invention covered by claims 13 and 19 would have been included in the original patent."

The Solicitor's brief concedes that some minimal support for claims 13 and 19 appears in the patent's specification, but argues that "mere disclosure of this subject matter does not demonstrate an intent to claim this subject matter." The Solicitor's brief also argues that "if a mistake was made [in not filing a divisional application], it is not the type of mistake which can be corrected by reissue," citing In re Orita, 550 F.2d 1277, 1281, 193 USPQ 145, 149 (CCPA 1977). [FN1]

B. The Board's Opinion

In its opinion, the board said, as above indicated, that the subject matter of claims 13 and 19 "was not claimed at all in the original application" (emphasis added), and that nothing in the patent evidenced an "intent to claim" that subject matter, citing In re Rowand, 526 f.2d 558, 560, 187 USPQ 487, 489 (CCPA 1975), as controlling authority.

This court reviews decisions, not the mere language of an opinion. When that language indicates an erroneous basis for the decision, the decision will be reversed, but that is not the case here. The board's language, while infelicitous, simply meant that Weiler's failure to have ever claimed, broadly or narrowly or otherwise, the subject matter of claims 13 and 19, and his failure to show an "intent to claim" that subject matter, indicated absence of the statutorily required "error."

The board's language reflected its well founded recognition that Weiler was seeking to claim subject matter entirely distinct from anything anywhere earlier claimed or attempted or intended to be claimed, and was not seeking to obtain a broadened or narrowed claim to subject matter claimed in the patent proffered for surrender. In dealing with that more common circumstance, one of our predecessor courts said "the whole purpose of the [reissue] statute, so far as claims are concerned, is to permit limitations to be added to claims that are too broad or to be taken from claims that are too narrow."In re Handel, 312 F.2d 943, 948, 136 USPQ 460, 464 (CCPA 1963).

C. Disclosure

Weiler argues, on the basis of loose language which, taken out of context, would appear to say that one looks only to see whether the subject matter of a reissue claim appears in the disclosure, and, if it does, a reissue applicant must be granted allowance of that claim. See D. Chisum, Patents, § 15.03[3] at 15-53 (1985); I. Kayton, Kayton on Patents, § 22-64 (1985). But the question of support in the ***676** disclosure is a § 112 inquiry. If there be no such support, the inquiry ends there, and reissue cannot be obtained. Thus, all consideration of § 251 must await that threshold § 112 determination. In the present case, as above indicated, there is some minimal support for the subject matter of claims 13 and 19.

When, unlike the present case, a reissue applicant seeks to obtain a broadened version of a claim in the patent, one may look to see whether the disclosure "reasonably conveys to one skilled in the art that the inventor had possession of the broad invention at the time the original application was filed."In re Peters, 723 F.2d 891, 894, 221 USPQ 952, 954 (Fed. Cir. 1984). That language speaks to the reason why the inventor failed to claim more broadly an invention he had claimed in the patent. It does not speak to the present case, in which Weiler did not claim the subject matter of the reissue claims "at all," to use the board's phrase. The language referring to the "disclosure" in Peters, and in other cases dealing with reissue, is directed ultimately to the question of error. One cannot assert error in failing to claim that which was not disclosed at all, or that which was not so disclosed as to indicate that the inventor was possessed of the invention as it is being claimed in the reissue application.

Weiler's argument that the subject matter of claims

13 and 19 does not constitute "an independent and distinct invention" merely because that subject matter can be found somewhere in the overall disclosure of the '923 patent is meaningless. As above indicated, the subject matter must have been disclosed, § 112, or there is no basis for discussing whether the invention being claimed on reissue is independent or distinct. Moreover, § 251 authorizes reissue for "the" invention disclosed in the original patent, not for just "any" and "every" invention for which one may find some support in the disclosure of the original patent.

The subject matter of claims 13 and 19 are clearly independent of and distinct from each other, from that of elected claims 1-7, from that of non- elected organic compound claims 8 and 11, and from that of non-elected protein compound claims 9 and 10. Weiler would thus have had no right to insert and present claims 13 and 19 in the original application after the examiner's requirement for restriction.

Here too, the question redounds to one of error, for when an applicant makes some disclosure, as Weiler did, of as many as five distinct inventions, claims one, and ignores the rest, it is difficult to find error in the failure to claim those ignored on the sole basis that they were disclosed. To so hold would render meaningless the statutory requirement that an appellant point out and distinctly claim subject matter he regards as his invention. 35 U.S.C. § 112, 2d P. [FN2]

D. "Intent to Claim"

Language appearing first in the opinion in U.S. Industrial Chemicals, Inc. v. Carbide & Carbon Chemicals Corp., 315 U.S. 668, 676, 53 USPQ 6, 9-10 (1942), has been picked up and has metamorphosed into a requirement that an applicant show his original "intent to claim" the subject matter of the reissue claim sought. The phrase "intent to claim" does not appear in the statute. It is but judicial shorthand, signifying a means of measuring whether the statutorily required error is present. Clearly, a showing that an applicant had an intent to claim matter he did not claim can go a long way to support a finding that error occurred; and, conversely, a showing that an applicant never had any such intent makes a finding of error extremely difficult if not impossible.

References to "intent to claim" in our cases, though occasionally including § 112 considerations, resolve ultimately into the question of error. "Determining what protection [an inventor] intended to secure by [an] original patent for the purposes of § 251 is an essentially factual inquiry confined to the objective intent manifested by the original patent."In re Rowand, 526 F.2d 558, 560, 187 USPQ 487, 489 (CCPA 1975) (emphasis in original). As explained in a later decision, Rowand's test of "intent to claim" was not one of "intent" per se, but looked to "objective indicia of intent."In re Mead, 581 F.2d 251, 256, 198 USPQ 412, 417 (CCPA 1978). The court in Mead *677 analogized that evidence of "intent" to the written description requirement of § 112, first paragraph, i.e., "a written description of the invention, and of the manner and process of making an using it."See also In re Peters, 723 F.2d 891, 894, 221 USPQ 952, 954 (Fed. Cir. 1984). It is true that absence of compliance with §112 will foreclose a finding of "intent" and preclude grant of the reissue, but, as indicated above, that absence dooms the application in any event. The converse is not true. Compliance with § 112 does not alone establish "intent to claim" and does not alone establish error in a failure to claim.[FN3]

This court has recently moved the "intent to claim" approach toward closer conformity with the statute, describing it as merely one factor "that sheds light upon whether the claims of the reissue application are directed to the same invention as the original patent and the reissue would correct an inadvertent error in the original patent." In re Hounsfield, 669 F.2d 1320, 1323, 216 USPQ 1045, 1048 (Fed. Cir. 1982) (emphasis added).

E. "Error"

Thus, we arrive at the central question in this appeal, which is not whether there is disclosure, but whether Weiler has established "error" which can be remedied by reissue. The reissue statute was not enacted as a panacea for all patent prosecution problems, nor as a grant to the patentee of a second opportunity to prosecute de novo his original application.

The language of U.S. Industrial Chemicals, Inc. v. Carbide & Carbon Chemicals Corp., 315 U.S. at 676, 53 USPQ at 9-10, is relevant here:

> [I]t is not enough that an invention might have been claimed in the original patent because it was suggested or indicated in the specification. It must

> appear from the face of the instrument that what is covered by the reissue was intended to have been covered and secured by the original. [Emphasis added.]

Weiler and the Solicitor argue as though the "error" to be corrected by reissue were a subjective error. It is not. We do not here deal with "deceptive intention".

Though the term "error" is to be interpreted liberally, In re Wessler, 367 F.2d 838, 849, 151 USPQ at 339, 348 (CCPA 1966), Congress did not intend to alter the test of "inadvertence, accident, or mistake" established in relation to the pre-1952 statutes. In re Wadlinger, 496 F.2d 1200, 1207, 181 USPQ 826, 831 (CCPA 1974). See In re Mead, 581 F.2d 251, 257, 198 USPQ 412, 418 (CCPA 1978) ("conscious choice" not to file continuing application not "error"); In re Clark, 522 F.2d 623, 626, 187 USPQ 209, 212 (CCPA 1975) (dereliction in duty of candor not "error"); In re Byers, 230 F.2d 451, 454, 109 USPQ 53, 55 (CCPA 1956) (deliberate amendment of claim not "error"). See also In re Petrow, 402 F.2d 485, 159 USPQ 449 (CCPA 1968) (cancellation of claim in original application was "error"); In re Willingham, 282 F.2d 353, 127 USPQ 211 (CCPA 1960) (cancellation of claim was "error").

As above indicated, the discussions in the briefs concerning the failure to assert the non-elected claims in a divisional application are irrelevant. Those claims are not on appeal and were drawn to subject matter distinct from that of claims 13 and 19. Though Weiler might have filed a divisional application containing claims 13 and 19, there is nothing of record remotely indicating that Weiler or his counsel or anyone else ever thought of doing so, or ever intended doing so, or failed to do so only through error.

Significantly, Weiler accepted issuance of the '923 patent with its claims to a single elected invention. By acquiescing in the examiner's restriction requirement, and failing to file divisional applications on the subject matter of non-elected claims, Weiler foreclosed (because that was not error) his right to claim that subject matter. If it were not error to forego divisional applications on subject matter to which claims had been made in the original application, it cannot on the present record have been error to forego divisional applications on subject matter to which claims had never been made. Nor has Weiler made any showing on which error could be found as the cause of his failure to claim the subject matter of claims 13 and 19. [FN4]

[1] ***678** The board's notation that the subject matter of claims 13 and 19 was "not claimed at all" in the original application, and its finding that nothing in the original patent evidences Weiler's "intent to claim" that subject matter, reflect non-statutory language used by courts and others to support and convey the concept that an inventor's failure to claim particular subject matter was not the result of the "error" required by § 251. Having made that notation and finding, the board should have stated the resulting basis (no error) for its decision. That it did not do so does not require reversal in this case, in which the record clearly supports the notation and finding, Weiler has not shown that either was clearly erroneous, and Weiler has shown nothing in the record that would have required the board to determine that his failure to claim the subject matter of claims 13 and 19 was the result of error.

AFFIRMED

FN1 Because the rejection of claims 14-18 is not appealed, the parties' discussion of the reasons why Weiler failed to file divisional applications on the subject matter of those claims, Weiler's evidence consisting of letters about divisional applications on non-elected claims 8-11, and the Solicitor's reliance on Orita, are irrelevant.

FN2 I. Kayton, Kayton on Patents, § 22-64 (1985) ("the predecessor to our present statute required that a reissue application be for 'the same invention' rather than for 'the invention disclosed' in the original patent . . . Now it is only necessary to compare the reissue claims with the disclosure in the parent patent for the purpose of determining whether they are supported as required by 35 USC § 112" (emphasis in original)). As indicated in the text, compliance with § 112 is a threshold consideration, but such compliance does not establish error in a failure to claim every disclosed.

FN3 One commentator has recently stated: "The intent test and the U.S. Industrial Chemicals statement [see text infra] are perhaps best understood as expressions of the 'description of the invention' requirement, which the Court of Customs and Patent Appeals recognizes as distinct from the enablement requirement," D. Chisum, Patents, § 15.03[3] at 15-53 (1985). The commentator could not have meant that compliance with § 112's

enablement requirement is sufficient in itself to warrant an automatic finding of "intent" and a resulting reissue, in disregard of § 251's requirement to show error.

FN4 Weiler's reliance on allegations of the inventors' ignorance of drafting and claiming technique and counsel's ignorance of the invention is unavailing. Those allegations could be frequently made, and, if accepted as establishing error, would require the grant of reissues on anything and everything mentioned in a disclosure. Weiler supplies no facts indicating how the ignorance relied on caused any error as the basis of his failure to claim the subject matter of claims 13 and 19. As indicated in the text § 251 does not authorize a patentee to re-present his application. Insight resulting from hindsight on the part of new counsel does not, in every case, establish error.

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U.S. Court of Appeals
Federal Circuit

Hester Industries Inc. v. Stein Inc.

Nos. 97-1352, -1353

Decided May 7, 1998

PATENTS

1. Practice and procedure in Patent and Trademark Office — Reissue — Error without deceptive intent (§110.1303)

Asserted reissue claims of patent for food cooker are broader than original claims within meaning of "recapture rule," which prohibits grant of reissue claims that are broader than original claims in manner directly pertinent to subject matter surrendered during prosecution, since reissue claim that does not include limitation present in original patent claims is broader in that respect, and since reissue claims in present case do not include two limitations of original claims that require cooking "solely with steam," supplied by "two sources of steam."

2. Practice and procedure in Patent and Trademark Office — Reissue — Error without deceptive intent (§110.1303)

Arguments made to overcome prior art, even when made in absence of any claim amendment, can evidence admission sufficient to give rise to finding of "surrender" within meaning of "recapture rule," which prohibits grant of reissue claims that are broader than original claims in manner directly pertinent to subject matter surrendered during prosecution, since view that arguments alone can give rise to surrender is consistent with policy behind reissue statute, 35 USC 251, which is based on fundamental principles of equity and fairness, and with accompanying recapture rule, which is based on principles of equity and therefore embodies notion of estoppel.

3. Practice and procedure in Patent and Trademark Office — Reissue — Error without deceptive intent (§110.1303)

Applicant surrendered claim scope for food cooker patent that does not include two limitations which require cooking "solely with steam," supplied by "two sources of steam," since applicant repeatedly argued, during prosecution of original patent, that "solely with steam" and "two sources of steam" limitations distinguished original claims from prior art, and that each of these limitations was "critical" to patentability, and since these repeated arguments constitute admission by applicant that limitations were necessary to overcome prior art.

4. Practice and procedure in Patent and Trademark Office — Reissue — Error without deceptive intent (§110.1303)

Determining whether subject matter surrendered by argument alone during prosecution of original patent has crept back into asserted reissue claims is accomplished by simply analyzing asserted reissue claims to determine whether they were obtained in manner contrary to arguments on which surrender was based; in present case, in which asserted reissue claims of patent for food cooker do not include two original claim limitations, which required cooking "solely with steam" supplied by "two sources of steam," surrendered subject matter, namely cooking other than solely with steam and with at least two sources of steam, has crept into reissue claims.

5. Practice and procedure in Patent and Trademark Office — Reissue — Error without deceptive intent (§110.1303)

Asserted reissue claims of patent for food cooker, which are broader in certain respects than claims of original patent, have not been materially narrowed in other respects so as to avoid operation of "recapture rule," since limitation in reissue claims requiring use of "high humidity steam" is actually same as or broader than corresponding limitation in original claim, since limitation in reissue claims requiring use of "spiral conveyance path" for conveyor belt of device is not materially limiting, in view of corresponding means-plus-function limitation in original claim, and since "spiral conveyance path" and "high humidity steam" limitations are not aspects of invention that were overlooked during prosecution of original patent.

6. Practice and procedure in Patent and Trademark Office — Reissue — Same invention (§110.1305)

"Original patent" clause of reissue statute, 35 USC 251, does not include separate requirement of objective intent to claim; rather, essential inquiry is whether one skilled in art, reading specification, would identify subject matter of new claims as invented and disclosed by patentee, and to extent construct of objective intent to claim is useful, it is only one factor which sheds light on whether original patent clause is satisfied.

Particular patents — General and mechanical — Cooker

Re. 33,510 (of 4,582,047), Williams, high humidity steam cooker with continuously running conveyor, judgment of invalidity affirmed.

Re. 33,259 (of 4,582,047), Williams, high humidity steam cooker with continuously running conveyor, judgment of invalidity affirmed.

Appeal from the U.S. District Court for the Eastern District of Virginia, Ellis, J.; 43 USPQ2d 1236.

Action by Hester Industries Inc. against Stein Inc. for patent infringement. Plaintiff appeals from grant of defendant's motion for summary judgment of patent invalidity, and defendant cross-appeals from pre-trial ruling in which district court adopted plaintiff's proposed claim construction. Summary judgment of invalidity affirmed; cross-appeal dismissed.

Robert W. Adams, Robert A. Vanderhye, James T. Hosmer, Robert W. Faris, and William J. Griffin, of Nixon & Vanderhye, Arlington, Va., for plaintiff-appellant.

Charles H. De La Garza, of Arnold, White & Durkee, Minneapolis, Minn.; L. Gene Spears and James C. Pistorino, Houston, Texas, for defendant-cross appellant.

Before Plager and Schall, circuit judges.[1]

Plager, J.

Hester Industries, Inc. ("Hester") appeals from a summary judgment of invalidity entered by the United States District Court for the Eastern District of Virginia. The district court ruled that the reissue patent claims asserted by Hester against Stein, Inc. ("Stein") are invalid for failing to meet the statutory "error" and "original patent" requirements for reissue patents set forth in 35 U.S.C. § 251 ¶ 1 (1994). *Hester Indus., Inc. v. Stein, Inc.*, 963 F. Supp. 1403 [43 USPQ2d 1236] (E.D. Va. 1997). Stein cross-appeals a pretrial oral ruling in which the district court adopted Hester's proposed construction of the claim term "high humidity steam."

Because the asserted reissue claims impermissibly recapture subject matter surrendered by Hester through deliberate arguments repeatedly made to the Patent Office to overcome prior art, we hold that Hester is barred from asserting "error" within the meaning of 35 U.S.C. § 251 ¶ 1. We accordingly affirm the summary judgment of invalidity. Because the asserted claims are invalid, we need not and do not reach the claim construction issue.

BACKGROUND

At issue in this case are two reissue patents, U.S. Patent No. Re. 33,510 (the "'510 reissue patent") and U.S. Patent No. Re. 35,259 (the "'259 reissue patent"). The two patents are reissues of the same original patent, U.S. Patent No. 4,582,047 (the "'047 patent" or "original patent"), which they replaced pursuant to 35 U.S.C. § 251.[2] The patents are directed to a high humidity steam cooker having a continuously running conveyor for cooking food items such as poultry and other meat products. Hester, a processor of pre-cooked poultry and other meat products, owns the patents, and Charles E. Williams ("Williams"), a Hester employee, is the sole named inventor. After the '259 reissue patent (the second reissue) issued in 1996, Hester sued Stein, a manufacturer of industrial appliances, for allegedly infringing several reissue claims in the two reissue patents.

The two reissue patents and the original patent have the same written description; the patents differ only with respect to their claims. That written description describes an industrial-size steam cooker for cooking large quantities of food products. The cooker is described as having a cooker chamber in which a steam atmosphere is maintained. The food products are carried through the cooker chamber on a conveyor belt that runs through a spiral path. The written description teaches that efficient cooking is achieved without the loss of humidity, flavor, or appearance by maintaining a water-drop-free steam atmosphere within the chamber at near 100°C and 100% humidity, at above atmospheric pressure.

Two separate sources of steam, one internal and one external, are described for main-

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[1] A member of the panel that heard argument in this case was unable to continue with consideration of the case because of recusal. Pursuant to Rule 47.11 of this court, the matter was decided by the remaining members of the panel.

[2] The district court noted that the issuance of two reissue patents for the same original patent was a "curiosity" that appeared to be unprecedented. *Hester*, 963 F. Supp. at 1405 n.2. However, the propriety of two reissues for the same patent was not addressed below and has not been raised on appeal. Accordingly, we express no opinion on the matter.

taining the steam atmosphere. The internal source of steam described is a pool of water on the floor of the cooker chamber, heated by a heating element in the pool. The external source described is a steam generator, located outside the cooker chamber and connected by pipes to various locations within the cooker chamber to inject steam at those locations. The written description states that the external steam source typically provides 25% of the steam, with the remainder provided by the internal source. '047 patent, col. 3, ll. 42-45, 57-59. The heating element in the internal steam source is controlled to maintain the desired amount of steam and pressure within the cooker chamber. *Id.* col. 3, ll. 59-63.

The section of the written description entitled DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT describes the cooking atmosphere thus:

> The cooking is solely with water droplet free steam near 100° C. and 100% humidity at a pressure above atmospheric. The high humidity atmosphere prevents losses of humidity of the product as it passes through the cooker and helps retain juices, essences and flavor of the product. Also it improves the heating steam interface heat exchange at the product surface for more efficient cooking.
>
> The higher pressure not only produces a pressure-cooker like cooking efficiency to the cooking process, but is critical in connection with the flavor and conveyor type product flow as well.

Id. col. 3, ll. 22-33.

The original patent contains one independent claim, claim 1, directed to a food cooking system. The claim specifies that the cooking system cooks solely with steam and that the system includes two sources of steam to provide the steam atmosphere. Characteristics of the steam atmosphere are set forth, and the cooking system is said to include a means passing a conveyor belt through the cooker housing. Claim 1, with relevant text emphasized, reads:

> A food cooking system *cooking solely with steam* foods such as fish, fowl, meats or produce carried through a cooker on a continuously running conveyor belt, comprising in combination, a cooker housing, *means passing said conveyor belt through said housing* to expose food products within the cooker housing only to *said steam as the sole cooking medium*, and *two sources of steam providing said steam* to cook the food products, nozzles for releasing steam located inside said housing, one comprising a steam generator supplying supplemental steam into said housing at said nozzles located thereinside *to maintain the atmosphere together with the other steam source at near 100% humidity 100° C. and a pressure above atmospheric*, and the other source of steam comprising a pool of water within said housing with heating means for boiling the water to create steam.

Id. col. 5, l. 59 to col. 6, l. 8. For purposes here, this is substantially the same form in which the claim was first filed (as application claim 1) in the application for the original patent. Accordingly, we do not distinguish between the issued claim and the application claim, but instead simply refer to claim 1.

In addition to the independent claim, the original patent contains several claims which are dependent upon claim 1. Relevant here is dependent claim 12, which specifies in pertinent part: "A system as defined in claim 1 *wherein the conveyor belt is passed* inside said housing *in a spiral path* coiling downwardly. . . ." *Id.* col. 6, ll. 59-61 (emphasis added). This claim stemmed from original application claim 16, which specified that the conveyor belt is "passed . . . in a spiral path."

The application for the '047 patent (the original patent) was filed in 1979. The patent did not issue until 1986, nearly seven years later. Over the almost seven years in which the application was prosecuted before the United States Patent and Trademark Office ("Patent Office"), inventor Williams, through his attorney, repeatedly emphasized the "solely with steam" and "two sources of steam" features of the claimed invention in attempting to establish patentability over the prior art. For example, after the Examiner first rejected claim 1 as well as all the other claims as obvious, Office Action of Feb. 6, 1980, at 2, Williams distinguished a cited prior art cooker that cooked with a combination of infra-red dry heat and steam on the ground that the claimed invention cooked solely with steam, stating: "This principle is completely different from applicant's invention where the claims define cooking *solely* with steam." Applicant Response of Apr. 28, 1980 (emphasis in original). Williams also distinguished claim 1 on the basis of the "two sources of steam" limitation, the specified

characteristics of the steam atmosphere, and the recited continuously running conveyor belt. *Id.*

Application claim 16, which specified a spiral conveyance path, was rejected as obvious in view of an additional prior art cooker that included a spiral conveyor. Office Action of Feb. 6, 1980, at 4. In response, Williams amended claim 16 to specify further details of the spiral conveyance path and then argued that the claimed spiral conveyance path was distinguished from that shown in the prior art. Applicant Response of Apr. 28, 1980.

However, the Examiner continued to reject all claims as obvious. Office Action of July 9, 1980. At that point, Williams placed even greater reliance on the "solely with steam" and "two sources of steam" limitations in an attempt to overcome the obviousness rejection. For example, in his first appeal of the obviousness rejection to the Board of Patent Appeals and Interferences ("Board"), Williams stated, "The claimed system cooks *solely* with steam . . . by means of two separate and critical steam sources. . . ." Applicant Brief on Appeal, at 2 (Aug. 20, 1980) (emphasis in original). Later in the same brief, Williams specifically distinguished the cited prior art on the basis of these limitations:

> The primary reference Vischer cooks with IR radiation not steam. Clearly the claimed feature of cooking *solely* with steam is directly contrary to the teaching of the Vischer patent, which could therefore never make obvious any process or equipment cooking *solely* with steam as claimed.
>
> . . . .
>
> The Examiner errs in any implication that Jourdan shows two sources of steam.

Id. at 9-10 (emphasis in original).

Prior to the Board hearing Williams' appeal, the Examiner reopened prosecution on the merits in view of newly discovered prior art, thereby removing the appeal from the Board.[3] Office Action of Mar. 17, 1981. The Examiner then rejected all of the claims as obvious over the new prior art. *Id.* In response, Williams distinguished claim 1 over that prior art on the same bases, *i.e.*, the "solely with steam" and "two sources of steam" limitations. Applicant Response to Office Action (Apr. 17, 1981). However, the Examiner was not persuaded, even after these same arguments were repeated in subsequent papers submitted to the Patent Office.

Accordingly, Williams initiated a second appeal to the Board. He again emphasized the "solely with steam" and "two sources of steam" limitations. Applicant Brief on Appeal, at 13 (Dec. 22, 1981). He explained that the two sources of steam interact to provide a "synergy" that is "novel and nowhere suggested in any of the cited [prior] art." *Id.* Williams drove home his reliance on the "solely with steam" limitation most forcefully in his reply brief to the Board: "Clearly the Examiner reversibly errs as a matter of fact and in his efforts to make a case out against the *very material claimed feature that steam is the sole cooking medium (claim 1)*. Thus reversal is respectfully solicited." Applicant Reply Brief on Appeal, at 6 (Sep. 30, 1982) (emphasis in original).

The Board was persuaded and accordingly reversed the obviousness rejection in its opinion dated June 21, 1985, stating:

> [W]e find no suggestion in the combined teachings of the references which would have led the ordinarily skilled worker in the art to an apparatus utilizing steam as the sole cooking medium; utilizing two separate sources of steam, one of which includes a pool of water in the cooking chamber with means for boiling the water; and wherein the atmosphere within the cooking chamber is maintained above atmospheric by the two sources of steam.

Thereafter the claims were allowed and the application issued as the '047 patent on April 15, 1986.

On the two-year anniversary of the '047 patent's issuance, Williams applied for a reissue pursuant to 35 U.S.C. § 251, alleging that the patent claims had been drawn too narrowly due to attorney error. In the required oath accompanying the reissue application, Williams explained that he became aware of this alleged error after learning that Stein was in the process of developing a competing cooker in early 1988. According to his oath, Williams and his employer Hester concluded that the '047 patent should cover the Stein cooker, notwithstanding the fact that the cooker used a non-steam heat source and only one source of steam in the cooking process. Williams further explained that Hester's present counsel advised Hester that the '047 patent claims, as written, might not cover Stein's cooker. Thus, Williams, by oath, declared that the patent was insufficient because it claimed less than he had a right to claim.

[3] Accordingly, the Board never heard Williams' first appeal.

Specifically, Williams identified two relevant deficiencies of the '047 patent, as follows (indentation and numbering added):[4]

> [1] that each of claims 1-14 therein requires cooking "solely with steam" and exposing food products within the cooker housing "only to said steam as the sole cooking medium". . . . [and]
> [2] that each of claims 1-14 therein requires "two sources of steam providing said steam to cook the food products, nozzles for releasing steam located inside said housing"[.]

These deficiencies, according to Williams, "arose after [he] executed and filed the original application from which the '047 patent issued" and were caused by "the failure of [his prior] patent attorney . . . to appreciate the full scope of [his] invention."

This application ripened into the '510 reissue patent nearly three years later on January 1, 1991. However, prior to its issuance, Williams filed a second reissue application, for reasons not relevant here, on June 21, 1990, alleging the same errors used to support the first reissue. Six years later, this second reissue application issued as the '259 reissue patent. Hester then filed this action, accusing Stein of infringing two claims in the first reissue patent and six claims in the second. Specifically, Hester accused Stein of infringing reissue claims 26 and 59 of the '510 reissue patent and reissue claims 28, 30, 31, 32, 75, and 76 of the '259 reissue patent.

The requirement in original claim 1 that cooking is "solely with steam" is absent from each of the asserted reissue claims. Also absent is the "two sources of steam" limitation. Rather, the asserted reissue claims merely recite a source of steam or at least one source of steam. None of the asserted reissue claims explicitly recite the steam atmosphere characteristics specified in original claim 1, *i.e.*, the characteristics of near 100°C and 100% humidity at above atmospheric pressure. Instead, all but one of the asserted reissue claims recite "high humidity steam."[5]

Claim 26 of the '510 reissue patent is representative of the two asserted reissue claims in that patent. It provides in pertinent part:

> A food cooking system for cooking food products carried on a moving conveyor belt, comprising:
> a cooker housing[,]
> *means disposed within said housing for defining a conveyance path*,
> a conveyor belt disposed along said conveyance path for supporting and conveying said food products along said path,
> means coupled to said belt for causing said belt and said food products supported thereby to substantially continually translate along said conveyance path . . . , and
> *a source of steam providing steam to contact and cook the food products, said steam source comprising at least one of the following*:
> an external steam generator supplying steam into said housing, and
> a pool of water within said housing with heating means communicating with said pool of water for creating steam. . . . [,]
> *wherein said steam source provides high humidity steam* and said food products are directly exposed to said high humidity steam.

'510 patent, col. 8, ll. 8-31, 36-38 (emphasis added, and text of claim 24, upon which claim 26 depends, incorporated).

The asserted reissue claims of the '259 reissue patent are, for purposes here, substantially similar. One difference is that several of these claims explicitly recite a "spiral conveyance path." Claim 28, which is representative, provides in pertinent part:

> A spiral steam cooker for at least partially cooking exposed food products, said cooker comprising:
> a housing defining an internal volume therein;
> a conveyor belt at least partially *disposed along a spiral conveyance path* within said internal volume . . . ; and
> *a steam source* operatively coupled to said housing, said steam source *providing a high humidity steam atmosphere* within said internal volume, said high humidity steam atmosphere directly contacting and at least partially cooking the exposed food products . . . .

'259 patent, col. 9, l. 61 to col. 10, l. 12 (emphasis added).

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[4] The reissue oath specifies two further insufficiencies, namely, that the '047 patent requires:

> [3] "a steam generator supplying supplemental steam into said housing at said nozzles located thereinside to maintain the atmosphere together with the other steam source at near 100% humidity 100° C and a pressure above atmospherec" and
>
> [4] "a pool of water within the housing with heating means for boiling the water to create steam."

(Indentation and numbering added.)

[5] Claim 30 of the '259 reissue patent does not contain the "high humidity steam" language.

Before the district court, Stein moved for summary judgment that the asserted reissue claims are invalid for failing to meet the requirements of the reissue statute, 35 U.S.C. § 251. That section (with emphasis added) reads:

> Whenever any patent is, through *error* without any deceptive intention, deemed wholly or partly inoperative or invalid, by reason of a defective specification or drawing, or *by reason of the patentee claiming more or less than he had a right to claim in the patent*, the Commissioner shall, on the surrender of such patent and the payment of the fee required by law, reissue the patent *for the invention disclosed in the original patent*, and in accordance with a new and amended application, for the unexpired part of the term of the original patent. No new matter shall be introduced into the application for reissue.

In particular, Stein argued that the "error" requirement of § 251 ¶ 1, as well as the requirement therein that the reissue claims be "for the invention disclosed in the original patent" (the "original patent" requirement), were not met. With regard to the "error" requirement, Stein argued that Williams had not erred in including the "solely with steam" and "two sources of steam" limitations in the original claims, and further argued that the removal of those limitations violated the "recapture" rule. Stein further argued that the asserted reissue claims violated the "original patent" requirement because, Stein asserted, the original patent does not evidence an "objective" intent to claim the invention in the manner of the asserted reissue claims.

The district court granted Stein's motion. The court first concluded that there was no "error" as contemplated by § 251 ¶ 1. Specifically, the court concluded that the alleged failure of counsel to appreciate the scope of the invention was belied by the clear language in the original patent claims, the prosecution history of the patent, and the absence of any explanation as to the nature or cause of the attorney's failure to appreciate the full scope of the invention. *Hester*, 963 F. Supp. at 1408. The court did not reach Stein's assertion that the asserted reissue claims violate the recapture rule, though the court relied heavily on the original patent's prosecution history in determining that the "error" requirement was not met. *See id.* at 1409-11.

The district court ruled that the asserted reissue claims are alternatively invalid for failing to meet the "original patent" requirement. *Id.* at 1412. The district court concluded that the "original patent" clause of § 251 ¶ 1 includes a separate requirement that the original patent manifest an "objective" intent to claim the invention as later claimed on reissue. *Id.* at 1412-13 The court concluded that the original patent does not manifest such an objective intent, and thus the claims are also invalid under the "original patent" clause of § 251 ¶ 1. *Id.* at 1412-15.

In its appeal of the invalidity judgment, Hester argues that the district court erred in concluding that the "error" and "original patent" requirements of § 251 ¶ 1 were not met. Stein, in seeking to uphold the judgment, makes the same arguments presented to the district court in its motion for summary judgment. Hester, on the other hand, argues that the "error" requirement was met by way of prior patent counsel's failure to appreciate the full scope of the invention. Hester further asserts that the recapture rule is inapplicable because the reissue claims were never presented during prosecution of the original patent and later abandoned by amendment or cancellation. With regard to the "original patent" clause of § 251 ¶ 1, Hester submits that there is no separate requirement of a manifestation of an objective intent to claim.

Also at issue on appeal is the district court's resolution of a "Motion For Claim Interpretation" brought by Stein. In that motion, Stein argued that the claim term "high humidity steam" should be construed in accordance with the only specific description of the steam atmosphere provided in the patents, *i.e.*, as water-droplet-free steam near 100°C and 100% humidity at above atmospheric pressure. Hester, relying on the opinion of its expert, proposed a broader construction, arguing that the description contained in the patents is merely one example of "high humidity steam." The district court, in a ruling delivered from the bench prior to holding the asserted reissue claims invalid, adopted Hester's proposed construction of the claim term. The ruling was never reduced to a formal order or judgment. The parties, by way of cross-appeal by Stein, present the same issue on appeal.

DISCUSSION

I

In reviewing the summary judgment of invalidity, we keep in mind that summary judgment is appropriate only when the record shows that "there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of

law." Fed. R. Civ. P. 56(c). Whether the statutory requirements of 35 U.S.C. § 251 have been met is a question of law. *See In re Clement*, 131 F.3d 1464, 1468, 45 USPQ2d 1161, 1163 (Fed. Cir. 1997). This legal conclusion can involve underlying factual questions. *See id.*

II

As previously explained, the "error" and "original patent" requirements at issue here are found in the first paragraph of § 251. The "error" requirement limits the availability of a reissue patent to certain correctable errors. *See In re Amos*, 953 F.2d 613, 616, 21 USPQ2d 1271, 1273 (Fed. Cir. 1991). As seen in the above-emphasized text of § 251, one such correctable error is the patentee claiming his invention too broadly or too narrowly.[6] *See id.*

The "original patent" requirement is a second and independent requirement, *see Amos*, 953 F.2d at 615, 21 USPQ2d at 1272, which restricts a reissue patent to "the invention disclosed in the original patent." 35 U.S.C. § 251 ¶ 1. We address each of these requirements in turn.

A

1

In considering the "error" requirement, we keep in mind that the reissue statute is "based on fundamental principles of equity and fairness, and should be construed liberally." *In re Weiler*, 790 F.2d 1576, 1579, 229 USPQ 673, 675 (Fed. Cir. 1986). We also keep in mind that "not every event or circumstance that might be labeled 'error' is correctable by reissue." *Id.* Indeed, the reissue procedure does not give the patentee the right "to prosecute *de novo* his original application." *Id.* at 1582, 229 USPQ at 677; *see also Mentor Corp. v. Coloplast, Inc.*, 998 F.2d 992, 995, 27 USPQ2d 1521, 1524 (Fed. Cir. 1993).

One of the most commonly asserted "errors" in support of a broadening reissue is the failure of the patentee's attorney to appreciate the full scope of the invention during the prosecution of the original patent application. *See Amos*, 953 F.2d at 616, 21 USPQ2d at 1273; *In re Wilder*, 736 F.2d 1516, 1519, 222 USPQ 369, 371 (Fed. Cir. 1984). This form of error has generally been accepted as sufficient to satisfy the "error" requirement of § 251. *See Clement*, 131 F.3d at 1468, 45 USPQ2d at 1163; *Wilder*, 736 F.2d at 1519, 222 USPQ at 371. Williams asserted this form of error as the basis for his reissue applications, and the Patent Office accepted his assertion as adequate.

However, the district court concluded that there was no such error by Williams' attorney. *Hester*, 963 F. Supp. at 1411. In reaching this conclusion, the court was particularly persuaded by the prosecution history of the original patent. The court concluded that the attorney's repeated attempts to distinguish Williams' invention on the basis of the "solely with steam" and "two sources of steam" limitations belied Williams' assertion that his attorney failed to appreciate the full scope of his invention. *Id.* at 1409-11. The court also determined that there was no other form of § 251 "error" and thus held the asserted reissue claims invalid. *Id.* at 1411-12.

2

We share the district court's discomfort with Williams' attempt to remove, through reissue, the "solely with steam" and "two sources of steam" limitations after having relied so heavily on those limitations to obtain allowance of the original patent claims over the prior art. This concern is addressed most squarely by the "recapture rule," recently discussed at length in *Clement*, 131 F.3d 1464, 45 USPQ2d 1161. The recapture rule "prevents a patentee from regaining through reissue . . . subject matter that he surrendered in an effort to obtain allowance of the original claims." *Clement*, 131 F.3d at 1468, 45 USPQ2d at 1164. The rule is rooted in the "error" requirement in that such a surrender is not the type of correctable "error" contemplated by the reissue statute. *See Mentor*, 998 F.2d at 995-96, 27 USPQ2d at 1525.

In its motion for summary judgment, Stein presented the recapture rule as one basis for finding the asserted reissue claims invalid, and Stein repeats this argument on appeal as one basis for affirming the summary judgment of invalidity. While the district court did not explicitly rule on this ground, its opinion indicates the view that Hester, through the reissue patents, recaptured surrendered subject matter. *Hester*, 963 F. Supp. at 1412 (stating that through the reissues, Hester obtained claims covering

[6] The last paragraph of § 251 requires that a request to enlarge the scope of claims be "applied for within two years from the grant of the original patent." 35 U.S.C. § 251 ¶ 4 (1994).

"ovens with characteristics repeatedly distinguished and disclaimed in the PTO" and that that was contrary to the "error" requirement of § 251). As will be next explained, we conclude that the asserted reissue claims violate the recapture rule and that the summary judgment ruling is appropriately affirmed on this ground.

[1] "Under [the recapture] rule, claims that are 'broader than the original patent claims in a manner directly pertinent to the subject matter surrendered during prosecution' are impermissible." *Clement*, 131 F.3d at 1468, 45 USPQ2d at 1164 (quoting *Mentor*, 998 F.2d at 996, 27 USPQ2d at 1525). Application of the recapture rule begins with a determination of whether and in what respect the reissue claims are broader than the original patent claims. *See id.* A reissue claim that does not include a limitation present in the original patent claims is broader in that respect. *See id.* Here, it is undisputed that the asserted reissue claims are broader than the original patent claims in that the reissue claims do not include the "solely with steam" and "two sources of steam" limitations found in each of the original patent claims.

Having determined that the reissue claims are broader in these respects, under the recapture rule we next examine whether these broader aspects relate to surrendered subject matter. *See id.* at 1468-69, 45 USPQ2d at 1164. "To determine whether an applicant surrendered particular subject matter, we look to the prosecution history for *arguments* and changes to the claims made in an effort to overcome a prior art rejection." *Id.* at 1469, 45 USPQ2d at 1164 (emphasis added). This statement in *Clement* indicates that a surrender can occur by way of arguments *or* claim changes made during the prosecution of the original patent application. To date, the cases in which this court has found an impermissible recapture have involved claim amendments or cancellations. *See, e.g., id.* at 1469-70, 45 USPQ2d at 1164-65; *Mentor*, 998 F.2d at 995-96, 27 USPQ2d at 1524-25. However, in addition to the suggestion in *Clement* that argument alone can effect a surrender, this court expressly left open that possibility in *Ball Corp. v. United States*: "If reissue is sought where claims have not been previously canceled, analysis becomes more difficult. In that case relative claim scope is not available to illuminate the alleged error. We are not faced with that situation in this proceeding." 729 F.2d 1429, 1436 n.19, 221 USPQ 289, 295 n.19 (Fed. Cir. 1984). Prior to this case, this court has not squarely addressed the question.

This court's prior opinions indicate that, as a general proposition, in determining whether there is a surrender, the prosecution history of the original patent should be examined for evidence of an admission by the patent applicant regarding patentability. *See Clement*, 131 F.3d at 1468, 45 USPQ2d at 1164 (noting that, with regard to claim amendments, the recapture rule does not apply in the absence of evidence that the amendment was an admission that the scope of the claim was not patentable); *Mentor*, 998 F.2d at 995, 27 USPQ2d at 1524 (same); *Seattle Box Co. v. Industrial Crating & Packing, Inc.*, 731 F.2d 818, 826, 221 USPQ 568, 574 (Fed. Cir. 1984) (declining to apply the recapture rule when there was no evidence that the "amendment . . . was in any sense an admission that the scope of [the] claim was not patentable"). In this regard, claim amendments are relevant because an amendment to overcome a prior art rejection evidences an admission that the claim was not patentable. *See Mentor*, 998 F.2d at 995-96, 27 USPQ2d at 1524-25 (finding surrender by way of claim amendments); *Ball*, 729 F.2d at 1436, 221 USPQ at 294 (noting that a court may draw inferences from changes in claim scope).

[2] Arguments made to overcome prior art can equally evidence an admission sufficient to give rise to a finding of surrender. Indeed, in *Mentor* and *Clement* the findings of a surrender were based in part on the arguments made in conjunction with the claim amendments. *Mentor*, 998 F.2d at 995-96, 27 USPQ2d at 1524-25; *Clement*, 131 F.3d at 1470-71, 45 USPQ2d at 1165-66. Logically, this is true even when the arguments are made in the absence of any claim amendment. Amendment of a claim is not the only permissible predicate for establishing a surrender.

The view that arguments alone can give rise to a surrender is consistent with the policy behind the reissue statute and the accompanying recapture rule. As already noted, the reissue statute is "based on fundamental principles of equity and fairness." *Weiler*, 790 F.2d at 1579, 229 USPQ at 1675. There is no unfairness in binding the patentee to deliberate assertions made in order to obtain allowance of the original patent claims over the prior art. Indeed, fairness to the public must also be considered. In this regard, as stated in *Mentor*, "the reissue statute cannot be construed in such a way that competitors, properly relying on prosecution history, become patent infringers when they do so." 998 F.2d at 996, 27 USPQ2d at 1525. The recapture rule operates to prevent this from happening. *See*

id. Furthermore, as recognized in *Ball*, the recapture rule is based on principles of equity and therefore embodies the notion of estoppel. 729 F.2d at 1439, 221 USPQ at 296.

Indeed, the recapture rule is quite similar to prosecution history estoppel, which prevents the application of the doctrine of equivalents in a manner contrary to the patent's prosecution history. *See Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 117 S. Ct. 1040, 1051 [41 USPQ2d 1865] (1997). Like the recapture rule, prosecution history estoppel prevents a patentee from regaining subject matter surrendered during prosecution in support of patentability. *See id.*

Hester argues that an analogy cannot be made with prosecution history estoppel because the reissue procedure and prosecution history estoppel are the antithesis of one another — reissue allows an expansion of patent rights whereas prosecution history estoppel is limiting. However, Hester's argument is unpersuasive. The analogy is not to the broadening aspect of reissues. Rather, the analogy is with the recapture rule, which restricts the permissible range of expansion through reissue just as prosecution history estoppel restricts the permissible range of equivalents under the doctrine of equivalents.

This court earlier concluded that prosecution history estoppel can arise by way of unmistakable assertions made to the Patent Office in support of patentability, just as it can by way of amendments to avoid prior art. *See, e.g., Texas Instruments, Inc. v. International Trade Comm'n*, 998 F.2d 1165, 1174, 26 USPQ2d 1018, 1025 (Fed. Cir. 1993). The same reasoning that led us to conclude that arguments alone can give rise to prosecution history estoppel lends support to the proposition that arguments alone can give rise to a surrender for purposes of the recapture rule.

Thus we conclude that, in a proper case, a surrender can occur through arguments alone. We next evaluate whether such a surrender occurred here with respect to the "solely with steam" and "two sources of steam" limitations, the pertinent aspects in which the asserted reissue claims are broader than the original patent claims. The obvious conclusion is that there has been a surrender.

[3] As detailed above, Williams repeatedly argued that the "solely with steam" and "two sources of steam" limitations distinguished the original claims from the prior art. These were Williams' primary bases for distinguishing the broadest claim, independent claim 1, from the prior art. At no less than 27 places in six papers submitted to the Patent Office, Williams asserted that the "solely with steam" limitation distinguished the claimed invention from the prior art, and Williams did the same with respect to the "two sources of steam" limitation at no less than 15 places in at least five papers.

Williams argued that each of these limitations was "critical" with regard to patentability, and Williams further stated that the "solely with steam" limitation was "very material" in this regard. In essence, these repeated arguments constitute an admission by Williams that these limitations were necessary to overcome the prior art. Indeed, when the Board reversed the Examiner's rejection of the original claims, these were the primary bases indicated for patentability. Williams, through his admission effected by way of his repeated prosecution arguments, surrendered claim scope that does not include these limitations.

[4] Having concluded that there has been a surrender, we must next determine whether the surrendered subject matter has crept back into the asserted reissue claims. *See Clement*, 131 F.3d at 1469, 45 USPQ2d at 1164. When the surrender occurs by way of claim amendment or cancellation, "[c]omparing the reissue claim with the canceled claim is one way to do this." *See id.* This analysis is not available when the surrender is made by way of argument alone. Instead, in this case, we simply analyze the asserted reissue claims to determine if they were obtained in a manner contrary to the arguments on which the surrender is based.

Clearly they were. None of the asserted reissue claims include either the "solely with steam" limitation or the "two sources of steam" limitation. Thus, this surrendered subject matter — *i.e.*, cooking other than solely with steam and with at least two sources of steam — has crept into the reissue claims. The asserted reissue claims are unmistakably broader in these respects.

Finally, because the recapture rule may be avoided in some circumstances, we consider whether the reissue claims were materially narrowed in other respects. *See, e.g., Mentor*, 998 F.2d at 996, 27 USPQ2d at 1525 ("Reissue claims that are broader in certain respects and narrower in others may avoid the effect of the recapture rule."); *Clement*, 131 F.3d at 1470, 45 USPQ2d at 1165. For example, in *Ball* the recapture rule was avoided because the reissue claims were sufficiently narrowed (described by the court as "fundamental narrowness") despite the broadened aspects of the claims. 729 F.2d at 1438; 221 USPQ at 296. In the context of a surrender by way of argument, this principle, in appropriate cases, may operate to overcome the recapture rule when the reissue

claims are materially narrower in other overlooked aspects of the invention. The purpose of this exception to the recapture rule is to allow the patentee to obtain through reissue a scope of protection to which he is rightfully entitled for such overlooked aspects.

[5] However, this is not such a case. The asserted reissue claims are not materially narrower, despite Hester's arguments to the contrary. Hester argues that the claims are materially narrower by the addition of the "spiral conveyance path" and "high humidity steam" limitations. The term "high humidity steam" is included in each of the asserted reissue claims except reissue claim 30 of the '259 reissue patent. However, the term "high humidity steam" is actually the same as or broader than the limitation in original claim 1 that this term replaced. Original claim 1 specifies a steam atmosphere "at near 100% humidity 100° C. and a pressure above atmospheric." '047 patent, col. 6, ll. 3-4. Hester concedes that the term "high humidity steam" is not narrower than this limitation in original claim 1. In fact, with respect to the claim construction issue, Hester argues that the limitation in original claim 1 is but one example of "high humidity steam." Accordingly, the use of the term "high humidity steam" does not save the reissue claims from the recapture rule.

The term "spiral conveyance path" is also not materially limiting. This term appears explicitly in asserted reissue claims 28, 32, 75, and 76 of the '259 reissue patent; it does not appear explicitly in the other reissue claims asserted. Original claim 1 includes a corresponding limitation, namely, "means passing said conveyor belt through said housing. . . ." This is a so-called means-plus-function clause drafted pursuant to 35 U.S.C. § 112 ¶ 6 (1994).[7] According to § 112 ¶ 6, the clause is to be construed to "cover the corresponding structure . . . described in the specification and equivalents thereof." The only corresponding structure described in the specification (more properly, the written description of the patent) passes the conveyor belt through a spiral path. *See* '047 patent, col. 4, l. 64 to col. 5, l. 8. Thus, the explicit recitation of a "spiral conveyance path" in some of the asserted reissue claims does not materially narrow those claims. Indeed, Hester does not explain how the explicit recitation of a spiral conveyance path—which is present in prior art cookers cited by the examiner during the prosecution of the original patent—materially narrows these claims. In sum, neither alone nor together do the terms "high humidity steam" and "spiral conveyance path" materially narrow the claims.

Furthermore, the "spiral conveyance path" and "high humidity steam" limitations are not aspects of the invention that were overlooked during prosecution of the original patent. To the contrary, as just explained, these aspects were included in original claim 1. Additionally, with regard to the "spiral conveyance path" limitation, original dependent claim 12 explicitly recites "a spiral path." '047 patent, col. 6, l. 60. In prosecuting the original patent, Williams pointed out these features in an attempt to overcome the Examiner's obviousness rejection. Hester cannot now argue that Williams overlooked these aspects during the prosecution of the original patent application. In conclusion, this is not a case which involves the addition of material limitations that overcome the recapture rule.

In effect, Hester, through eight years of reissue proceedings, prosecuted Williams' original patent application anew, this time placing greater emphasis on aspects previously included in the original patent claims and removing limitations repeatedly relied upon to distinguish the prior art and described as "critical" and "very material" to the patentability of the invention. The reissue statute is to be construed liberally, but not that liberally. The realm of corrections contemplated within § 251 does not include recapturing surrendered subject matter, without the addition of materially-narrowing limitations, in an attempt to 'custom-fit' the reissue claims to a competitor's product.

No doubt if two patent attorneys are given the task of drafting patent claims for the same invention, the two attorneys will in all likelihood arrive at somewhat different claims of somewhat different scope. And such differences are even more likely when, as here, the second attorney drafts the new claims nearly a decade later and with the distinct advantage of having before him the exact product offered by the now accused infringer. This reality does not justify recapturing surrendered subject matter under the mantra of "failure to appreciate the scope of the invention." The circumstances of the case before us simply do not fit within the concept of "error" as contemplated by the

[7] Use of the word "means" in a claim clause triggers a presumption that § 112 ¶ 6 applies. *See York Prods., Inc. v. Central Tractor Farm & Family Ctr.*, 99 F.3d 1568, 1574, 40 USPQ2d 1619, 1623-24 (Fed. Cir. 1996). The presumption can be overcome if the clause recites sufficient structure. *See id.* The clause at issue here recites no structure for performing the function of passing the conveyor belt through the housing. Accordingly, § 112 ¶ 6 unquestionably applies.

reissue statute. *See Mentor*, 998 F.2d at 996, 27 USPQ2d at 1525 ("Error under the reissue statute does not include a deliberate decision to surrender specific subject matter in order to overcome prior art, a decision which in light of subsequent developments in the marketplace might be regretted.").

With respect to the recapture issue, there are no underlying material facts as to which there is a genuine issue in dispute. The original patent's prosecution history, on which we rely, is before us and undisputed. All that remains is the ultimate legal conclusion as to whether the asserted reissue claims fail to meet the "error" requirement because the claims impermissibly recapture surrendered subject matter. *See id.* at 994, 27 USPQ2d at 1524 (stating that whether the "error" requirement has been met is a legal conclusion). For the reasons explained above, we conclude as a matter of law that the asserted reissue claims fail in this regard. Summary judgment of invalidity of the asserted reissue claims under § 251 is called for. Accordingly, we affirm the district court's entry of summary judgment.

B

As an alternative basis for holding the asserted reissue claims invalid, the district court concluded that the reissue claims do not meet the "original patent" clause of § 251 ¶ 1, which requires that the reissue patent be "for the invention disclosed in the original patent." *Hester*, 963 F. Supp. at 1412. In reaching this conclusion, the court interpreted the "original patent" clause as requiring an "objective" intent, manifested in the original patent, to claim the invention as claimed in the reissue patent. *Id.* The court based this interpretation on the Supreme Court's statement in *U.S. Industrial Chemicals, Inc. v. Carbide & Carbon Chemicals Corp.*, 315 U.S. 668, 676 [53 USPQ 6] (1942), that there was an objective intent requirement under the predecessor reissue statute, 35 U.S.C. § 64 (1964), which required that the reissue patent be "for the same invention." *Id.* at 1413.

Based on this construction of the "original patent" clause, the district court framed the issue as, "whether the 047 patent manifests an objective intent to cover ovens that utilize heat sources other than steam, and have less than two steam sources." *Id.* The district court concluded that the asserted reissue claims failed to meet this test and thus were invalid under the "original patent" clause. *Id.* at 1413-15. On appeal, the parties focus on whether the "original patent" clause embodies the requirement of an objective intent to claim.

[6] This court squarely addressed the issue in *Amos*, 953 F.2d at 616, 21 USPQ2d at 1273. The *Amos* court held that § 251 does not include a separate requirement of an objective intent to claim. 953 F.2d at 618-19, 21 USPQ2d at 1275-76. Rather, the court concluded: "the essential inquiry under the 'original patent' clause of § 251 . . . is whether one skilled in the art, reading the specification, would identify the subject matter of the new claims as invented and disclosed by the patentees." *Id.* at 618, 21 USPQ2d at 1275. The court noted that this inquiry is analogous to the "written description" requirement of 35 U.S.C. § 112 ¶ 1 (1994). *Id.* The court further stated that, to the extent the construct of an objective intent to claim is useful, it is "only one factor that sheds light" on whether the "original patent" clause of § 251 is satisfied. *Id.* at 619 & n.2, 21 USPQ2d at 1275-76 & n.2 (quoting *In re Hounsfield*, 699 F.2d 1320, 1323, 216 USPQ 1045, 1047-48 (Fed. Cir. 1983)).

With regard to the Supreme Court's opinion in *U.S. Industrial*, 315 U.S. 668, the *Amos* court noted that that case was decided under the predecessor reissue statute which required reissue claims to be for the "same invention," and concluded that *U.S. Industrial* does not now mandate a separate "objective intent to claim" requirement. *Id.* The *Amos* court noted that this court reached the same conclusion eight years earlier in *Hounsfield*, 699 F.2d at 1323, 216 USPQ at 1047-48. *Id.*

Thus, the district court's conclusion that the "original patent" clause of § 251 was not satisfied based on an "objective intent to claim" requirement was in error. Stein does not contend that the test set forth in *Amos* for the "original patent" clause — *i.e.*, whether one skilled in the art would identify the subject matter of the reissue claims as invented and disclosed by the patentee — is not met by the asserted reissue claims. Rather, Stein relies entirely on its assertion that there is an "objective intent to claim" requirement and that that requirement is not met. However, we need not resolve this issue further, having already concluded that the asserted reissue claims are invalid for failing to meet the "error" requirement of § 251.

III

Finally, Stein presents to us the question of whether the district court properly construed the claim term "high humidity steam." It is not immediately apparent whether this issue is properly before us. The

district court did not construe the term in conjunction with a final judgment, such as a summary judgment of noninfringment or invalidity. Rather, the district court issued an oral ruling on the matter in preparation for trial. However, the district court having held the asserted claims invalid on summary judgment, which we here affirm, there can be no question of liability and hence the claim construction issue is moot. Therefore, we need not decide whether Stein's appeal of the claim construction is proper, and if so, whether the district court's construction was correct.

CONCLUSION

We affirm the grant of summary judgment of invalidity of the asserted reissue claims for failure to comply with 35 U.S.C. § 251 ¶1. Stein's cross-appeal is dismissed.

COSTS

Each party shall bear its own costs.

AFFIRMED.

U.S. District Court
District of New Jersey

Jews for Jesus v. Brodsky

No. 98-274 (AJL)

Decided March 6, 1998

TRADEMARKS AND UNFAIR TRADE PRACTICES

1. Acquisition, assignment, and maintenance of marks — Scope of trademark — In general (§305.0201)

Infringement; conflicts between marks — In general (§335.01)

Owner of registered trademark "Jews for Jesus" has rights in phrase "Jews for Jesus" as used in Internet domain names, even though phrase does not contain stylized letter "O" in plaintiff's mark, since domain names, for technical reasons, cannot contain stylized letters, and since holding that mark owner lacks rights in phrase without registered mark's unique characteristic, such as script lettering or symbol, would enable party to use trademark of another where factors beyond control of mark's owner make it impossible to adequately depict mark.

2. Infringement; c nflicts between marks — Likelihood of confusion — Particular marks — Confusi n likely (§335.0304.03)

Phrase "jewsforjesus" in Internet domain name used by defendant appears to be confusingly similar to plaintiff's registered mark "Jews for Jesus," since exact similarities are not required between allegedly confusing marks in order to constitute infringement, and since, considering that defendant's domain name is nearly identical to plaintiff's mark, it is likely that Internet users will conclude that registered mark, name of plaintiff non-profit organization, and defendant's domain name share common source, affiliation, connection, or sponsorship.

3. Types of marks — Generic — Particular marks (§327.0603)

Common law service mark "Jews for Jesus" is not generic phrase for "Jews" who are "for Jesus," since during past 24 years, plaintiff non-profit organization has consistently used phrase to refer to organization itself, since there are several other names that could be used to refer to individuals of Jewish heritage who believe in Jesus, and since plaintiff's use of phrase does not leave so few alternatives as to monopolize concept and debilitate potential competitors.

4. Types of marks — Descriptive — Particular marks (§327.0303)

Common law service mark "Jews for Jesus" is descriptive, rather than suggestive, of organization whose members are individuals of Jewish heritage who believe in Jesus, since culling direct message from mark does not require much imagination or thought, and since mark does not conjure up purely arbitrary connotation.

5. Types of marks — Secondary meaning (§327.02)

Common law service mark "Jews for Jesus" used by plaintiff non-profit organization appears to have acquired secondary meaning, since plaintiff organization has expended considerable amount of money on advertising over past 10 years, has received extensive media coverage in connection with its teachings and mission, and has been successful in its marketing efforts, and since mark appears to have been in continuous use, by plaintiff and/or its predecessor organizations, since 1973.

U.S. C urt of Appeals
Federal Circuit

In re Clement

No. 97-1202

Decided December 12, 1997

PATENTS

1. Practice and procedure in Patent and Trademark Office — Reissue — Error without deceptive intent (§110.1303)

Attorney's failure to appreciate full scope of invention qualifies as error under 35 USC 251 and is correctable by reissue, but deliberate withdrawal or amendment does not involve inadvertence or mistake contemplated by Section 251, and recapture rule therefore prevents patentee from regaining, through reissue, subject matter surrendered in effort to obtain allowance of original claims; under this rule, reissue claims that are broader than original claims in manner directly pertinent to subject matter surrendered during prosecution are impermissible.

2. Practice and procedure in Patent and Trademark Office — Reissue — In general (§110.1301)

Recapture rule bars reissue claim if it is as broad as or broader than canceled or amended claim in all respects; if reissue claim is narrower in all respects, recapture rule does not apply, but other rejections are possible.

3. Practice and procedure in Patent and Trademark Office — Reissue — In general (§110.1301)

Recapture rule bars reissue claim that is broader than canceled or amended claim in some aspects, but narrower in others, if reissue claim is as broad or broader in aspect germane to prior art rejection, but narrower in another aspect completely unrelated to rejection; if reissue claim is narrower in aspect germane to prior art rejection, and broader in aspect unrelated to rejection, then recapture rule does not bar claim, but other rejections are possible.

4. Practice and procedure in Patent and Trademark Office — Reissue — Broader claims sought (§110.1313)

Recapture rule bars reissue claim of patent for method of producing pulp from waste paper, even though reissue claim is narrower than claim amended during prosecution in one area relevant to prior art rejection, since claim is also broader than amended claim, in that it eliminates several very specific process limitations which were added in order to distinguish invention over prior art, and since, on balance, reissue claim is broader than it is narrower in manner directly pertinent to subject matter that patentee surrendered during prosecution.

5. Practice and procedure in Patent and Trademark Office — Reissue — Br ader claims sought (§110.1313)

Recapture rule does not apply when broadening of reissue claim not only relates to aspect of issued claim that was never narrowed to overcome prior art, or argued as distinguishing claim from prior art, but also is not materially related to alleged error supporting reissue, but this rule does not require determination of whether broader aspects of reissue claims are related to alleged error.

6. Practice and procedure in Patent and Trademark Office — Reissue — In general (§110.1301)

Practice and procedure in Patent and Trademark Office — Reissue — Effect of grant or denial (§110.1309)

Rejection of reissue claims on ground of defective declaration is vacated, since claims, which are identical to those in issued patent, are not subject to recapture rule, and defective declaration thus would not invalidate them in and of itself, and since surrender of issued patent does not take effect until reissue patent issues, and claims therefore continue to exist with their normal presumption of validity unaffected by examiner's rejection based on allegedly defective declaration; however, claims identical to those in issued patent cannot alone support reissue application, and instant application would therefore fail to comply with 35 USC 251 even if patentee were to cure allegedly defective declaration.

Particular patents — Chemical — Waste paper treatment

4,780,179, Clement, method for producing pulp from printed unselected waste paper, rejection of reissue claims 49-52 affirmed; rejection of claims 1-18 vacated.

Appeal from the U.S. Patent and Trademark Office, Board of Patent Appeals and Interferences.

Application (serial no. 08/054,951) of Jean-Marie Clement for reissue of patent no. 4,780,179. From decision sustaining rejection of application claims 1-18 and 49-52, applicant appeals. Affirmed in part and vacated in part.

Lawrence M. Green and Christopher S. Schultz, of Wolf, Greenfield & Sacks, Boston, Mass., for appellant.

John M. Whealan, associate solicitor, U.S. Patent and Trademark Office, Nancy J. Linck, solicitor, Albin F. Drost, deputy solicitor, and Scott A. Chambers, associate solicitor, for appellee.

Before Mayer, circuit judge, Smith, senior circuit judge, and Clevenger, circuit judge.

Mayer, J.

Jean-Marie Clement appeals the decision of the United States Board of Patent Appeals and Interferences sustaining the rejection of claims 1-18 and 49-52 in reissue application Serial No. 08/054,951 under 35 U.S.C. § 251 (1994). Because the board correctly applied the recapture rule to bar claims 49-52 and because claims 1-18 alone cannot support the reissue application, we affirm in part and vacate in part.

Background

This case is about U.S. Patent No. 4,780,179 (the '179 patent) issued to Jean-Marie Clement. The '179 patent claims a method for treating waste paper that removes "stickies," such as glues and plastics, under a first set of environmental conditions, before removing inks under a second set of environmental conditions.

The '179 patent issued from application Serial No. 06/822,943 (the '943 application), which was a continuation of application Serial No. 06/482,623 (the '623 application). During prosecution, Clement amended the claims to overcome U.S. Patent No. 4,360,402, issued to Ortner et al. (Ortner), and an article written by Michael Burns entitled "Waste Paper Preparation Plant and Systems," published in the June/-August 1973 issue of Paper Technology (Burns). The broadest of the '623 application's claims, original claim 1, recites:

> A method of treating a mixture of printed and contaminated waste paper in order to produce pulps for the use in the manufacture of pulp and paper boards, which method comprises:
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> (a) forming an aqueous pulp of said waste material at low temperature, low specific mechanical energy, thereby forming a pulpable slurry and releasing the non-ink contaminants from the surface of the paper but without dispersing them inside the fibrous suspension;
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> (b) separating the non-ink contaminants from the pulp by mechanical separation, without the use of froth floatation or solvent extraction or other process, using conventional screens and centrifugal cleaners and without any further application of strong shear forces to the pulp;
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> (c) softening of the ink particles vehicles and weakening of their bondings with the surface of the fibres by submitting the pulp at a consistency of more than 15% at the simultaneous actions of (A) high temperature — between 85 and 130°C. — (B) high shear forces and (C) at least one de-inking agent, under alcaline [sic] conditions;
>
> (d) detaching the ink particles from the surface of the fibres and dispersing them into the fibrous suspension by submitting the pulp to the simultaneous actions of (A) high temperature — between 85 and 130°C. — (B) high shear forces and (C) at least one chemical dispersing agent, under alcaline [sic] conditions;
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> (e) removing the free ink particles by means of the most appropriate known method and up to the degree of brightness required by the final use of the pulp.

In an effort to overcome Ortner, Clement submitted a preliminary amendment in the '943 application dated January 27, 1986, which replaced original claim 1 with claim 42. Claim 42 is limited to: (1) carrying out step (a) at room temperature; (2) using mechanical energy less than 50 KW.H/Ton in step (a); (3) removing the ink by applying a combination of high temperature between 85 and 130°C, mechanical energy greater than 50 KW.H/Ton, and a de-inking or chemical dispersing agent under alkaline conditions in steps (c) and (d), respectively; and (4) limiting the duration of steps (c) and (d) to between two and ten minutes. In this preliminary amendment, Clement argued that Ortner's process could not apply simultaneously the higher temperature and larger shear force (mechanical energy greater than 50 KW.H/Ton) recited in steps (c) and (d). Clement also argued that using a higher temperature in Ortner's process would prevent the final product from having the necessary brightness.

In response, the examiner withdrew the Ortner reference, but relied on Burns until Clement's amendments dated December 23, 1986, and June 29, 1987, and an examiner's amendment dated May 16, 1988, added the following limitations: (1) steps (a) and (b) remove substantially all the non-ink contami-

nants including the stickies; (2) steps (c) and (d) include strong alkaline conditions having a pH of at least 9; (3) the brightness of the final pulp in step (f) is at least 59 ISO; and (4) step (b) takes place at room temperature. The table at Appendix A shows claim 42 before the last two amendments. In his December 23, 1986, amendment, Clement specifically argued that Burns fails to disclose the strong alkaline conditions having a pH greater than 9 that he added to steps (c) and (d). In his June 29, 1987, amendment, he continued to traverse the examiner's assertion that Burns discloses removing the stickies at room temperature through the application of mechanical energy lower than 50 KW.H/Ton. The patent issued on October 25, 1988, with claim 42 becoming claim 1, as shown in the table at Appendix B.

On October 18, 1990, Clement filed reissue application Serial No. 07/600,012 (the '012 application). During prosecution of the '012 application, he admitted that he added "very specific process parameters" to issued claim 1 during prosecution of the '943 application "in order to distinguish over the prior art." Clement later abandoned the '012 application in favor of continuation reissue application Serial No. 08/054,951 (the '951 application), presently on appeal. The '951 application includes claims 1-18, which correspond to claims 1-18 of the '179 patent, and claims 49-52, which are admittedly broader than the '179 patent's claims. In his reissue declaration, Clement stated that as a result of his failure to understand the claims and his attorney's failure to appreciate the scope of his invention, claims 1-18 of the '179 patent are unduly limited because "step (a) recites forming the first fibrous suspension at room temperature by applying specific mechanical energy lower than 50 KW. H/Ton." In addition, "the temperature, mechanical energy and pH conditions set forth in steps (c) and (d)" unduly limit claim 1 and claims 2-18, which depend from it. Claim 49 eliminates these limitations and the room temperature limitation in the first claim's step (b). The table at Appendix B compares reissue claim 49 with claim 1 of the '179 patent with differences italicized.

The examiner rejected claims 49-52 under 35 U.S.C. § 251 [1] for being broadened in a reissue application filed outside the two year statutory period. The examiner also rejected claims 1-18 and 49-52 under section 251 for lacking a basis for reissue because recapture is not an error so correctable. The examiner found the reissue declaration defective under 37 C.F.R. § 1.175 (1997) because it failed not only to mention the error in step (b), but also to explain sufficiently how any of the errors arose. The examiner determined that these defects were not curable because the recapture rule applied. Clement appealed the examiner's final rejection to the United States Board of Patent Appeals and Interferences (the board).

The board determined that Clement filed his broadening reissue application timely. It further found that during prosecution of the '179 patent, Clement added temperature, mechanical energy, and pH limitations to overcome prior art rejections. The board noted that the temperature limitation in step (a) and the temperature and mechanical energy limitations in steps (c) and (d) "were argued by [Clement] to be features not suggested by Ortner or Burns and ... were accepted by the examiner as distinguishing over these references." It concluded that Clement implicitly admitted that "broader claims not restricted to ... [these limitations] were not patentable over the prior art represented by Ortner." The board found that claims 49-52 do not include these limitations and concluded that the reissue claims seek to broaden the patent in a manner directly pertinent to subject matter that Clement deliberately surrendered to overcome prior art rejections. It therefore sustained the rejection of claims 49-52 for failing to comply with 35 U.S.C. § 251, and the rejection of claims 1-18 and 49-52 based on a defective reissue declaration. Clement appeals.

Discussion

[1] Determining whether an applicant has met the statutory requirements of 35 U.S.C. § 251 is a question of law, which we review *de novo*. *Mentor Corp. v. Coloplast, Inc.*, 998 F.2d 992, 994, 27 USPQ2d 1521, 1524 (Fed. Cir. 1993). This legal conclusion is based on underlying findings of fact, which we sustain unless they are clearly erroneous. *In re Kemps*, 97 F.3d 1427, 1430, 40 USPQ2d 1309, 1312 (Fed. Cir. 1996); *Mentor*, 998 F.2d at 994, 27 USPQ2d at 1524. An attorney's failure to appreciate the full scope of the invention qualifies as an error under section 251 and is correctable by reissue. *In re Wilder*, 736 F.2d 1516, 1519, 222 USPQ 369, 370-71 (Fed. Cir. 1984). Never-

[1] Section 251 allows patentees to correct "errors" made during prosecution, such as claiming less than the patentee had a right to claim. A reissue patent may not, however, enlarge the scope of the claims unless the patentee files the reissue application within two years of the grant of the patent.

theless, "deliberate withdrawal or amendment . . . cannot be said to involve the inadvertence or mistake contemplated by 35 U.S.C. § 251." *Haliczer v. United States*, 356 F.2d 541, 545, 148 USPQ 565, 569 (Ct. Cl. 1966). The recapture rule, therefore, prevents a patentee from regaining through reissue the subject matter that he surrendered in an effort to obtain allowance of the original claims. *See Mentor*, 998 F.2d at 995, 27 USPQ2d at 1524. Under this rule, claims that are "broader than the original patent claims in a manner directly pertinent to the subject matter surrendered during prosecution" are impermissible. *Id.* at 996, 27 USPQ2d at 1525.

The first step in applying the recapture rule is to determine whether and in what "aspect" the reissue claims are broader than the patent claims. For example, a reissue claim that deletes a limitation or element from the patent claims is broader in that limitation's aspect. Clement argues that the board focused too much on the specific limitations that were omitted from the reissue claims. Although the scope of the claims is the proper inquiry, *In re Richman*, 409 F.2d 269, 274, 161 USPQ 359, 362 (CCPA 1969), claim language, including limitations, defines claim scope. *Abtox, Inc. v. Exitron Corp.*, 122 F.3d 1019, 1023, 43 USPQ2d 1545, 1548 (Fed. Cir. 1997); *Bell Communications Research, Inc. v. Vitalink Communications Corp.*, 55 F.3d 615, 619, 34 USPQ2d 1816, 1819 (Fed. Cir. 1995) ("[T]he language of the claim defines the scope of the protected invention."). Under *Mentor*, courts must determine in which aspects the reissue claim is broader, which includes broadening as a result of an omitted limitation. The board did not err by determining which limitations Clement deleted from the patent claims.

The second step is to determine whether the broader aspects of the reissue claims relate to surrendered subject matter. To determine whether an applicant surrendered particular subject matter, we look to the prosecution history for arguments and changes to the claims made in an effort to overcome a prior art rejection. *See Mentor*, 998 F.2d at 995-96, 27 USPQ2d at 1524-25; *Ball Corp. v. United States*, 729 F.2d 1429, 1436, 221 USPQ 289, 294-95 (Fed. Cir. 1984).

Although the recapture rule does not apply in the absence of evidence that the applicant's amendment was "an admission that the scope of that claim was not in fact patentable," *Seattle Box Co. v. Industrial Crating & Packing, Inc.*, 731 F.2d 818, 826, 221 USPQ 568, 574 (Fed. Cir. 1984), "the court may draw inferences from changes in claim scope when other reliable evidence of the patentee's intent is not available," *Ball*, 729 F.2d at 1436, 221 USPQ at 294. Deliberately canceling or amending a claim in an effort to overcome a reference strongly suggests that the applicant admits that the scope of the claim before the cancellation or amendment is unpatentable, but it is not dispositive because other evidence in the prosecution history may indicate the contrary.[2] *See Mentor*, 998 F.2d at 995-96, 27 USPQ2d at 1524-25; *Ball*, 729 F.2d at 1438, 221 USPQ at 296; *Seattle Box Co.*, 731 F.2d at 826, 221 USPQ at 574 (declining to apply the recapture rule in the absence of evidence that the applicant's "amendment . . . was in any sense an admission that the scope of [the] claim was not patentable"); *Haliczer*, 356 F.2d at 545, 148 USPQ at 569 (acquiescence in the rejection and acceptance of a patent whose claims include the limitation added by the applicant to distinguish the claims from the prior art shows intentional withdrawal of subject matter); *In re Willingham*, 282 F.2d 353, 354, 357, 127 USPQ 211, 213, 215 (CCPA 1960) (no intent to surrender where the applicant canceled and replaced a claim without an intervening action by the examiner). Amending a claim "by the inclusion of an additional limitation [has] exactly the same effect as if the claim as originally presented had been canceled and replaced by a new claim including that limitation." *In re Byers*, 230 F.2d 451, 455, 109 USPQ 53, 55 (CCPA 1956).

Once we determine that an applicant has surrendered the subject matter of the canceled or amended claim, we then determine whether the surrendered subject matter has crept into the reissue claim. Comparing the reissue claim with the canceled claim is one way to do this. *In re Wadlinger*, 496 F.2d 1200, 1204, 181 USPQ 826, 830 (CCPA 1974); *Richman*, 409 F.2d at 274, 161 USPQ at 362. If the scope of the reissue claim is the same as or broader than that of the canceled claim, then the patentee is clearly attempting to recapture surrendered subject matter and the reissue claim is,

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[2] For example, if an applicant amends a broad claim in an effort to distinguish a reference and obtain allowance, but promptly files a continuation application to continue to traverse the prior art rejections, circumstances would suggest that the applicant did not admit that broader claims were not patentable — assuming that the applicant does not ultimately abandon the continuation application because the examiner refuses to withdraw the rejections.

therefore, unallowable. *Ball*, 729 F.2d at 1436, 221 USPQ at 295 ("The recapture rule bars the patentee from acquiring, through reissue, claims that are the same or of broader scope than those claims that were canceled from the original application.") (emphasis omitted); *Byers*, 230 F.2d at 456, 109 USPQ at 56. In contrast, a reissue claim narrower in scope escapes the recapture rule entirely. *Ball*, 729 F.2d at 1436, 221 USPQ at 295.

Some reissue claims, however, are broader than the canceled claim in some aspects, but narrower in others. In *Mentor*, for example, the issued claim, which was directed to a condom catheter, recited an adhesive means that was transferred from an outer to an inner surface without turning the condom inside-out. 998 F.2d at 993, 27 USPQ2d at 1523. The issued claim also recited, *inter alia*, that the condom catheter included a "thin cylindrical sheath member of resilient material rolled outwardly upon itself to form consecutively larger rolls . . . ." One canceled claim recited an adhesive means between the rolls, but did not specify that the adhesive was transferred from the outer to the inner surface without turning the condom inside-out. Another canceled claim recited that adhesive was transferred from the outer to the inner surface, but did not specify that this operation was done without turning the condom inside-out. The prior art rejections focused on the obviousness of the adhesive means positioned between the rolls and the process of transferring adhesive to the inner surface of the condom.

In making amendments to the claim, the applicant argued that "none of the references relied upon actually showed the *transfer of adhesive* from the outer surface to the inner surface as the sheath is rolled up and then unrolled." *Id.* at 995-96, 27 USPQ2d at 1524-25 (emphasis in original). The reissue claim eliminated the limitation that adhesive was transferred from the outer to the inner layer, and was, therefore, broader in this aspect. The reissue claim was also narrower than the canceled claim because it recited that the catheter included "a thin, *flexible* cylindrical member of resilient material rolled outwardly upon itself to form *a single roll*. . . ." (Emphasis added). We held that, although the "flexible" and "single roll" limitations made the reissue claim narrower than both the canceled and issued claims, it did not escape the recapture rule because these limitations did not "materially narrow the claim[ ]." *Id.* at 996-97, 27 USPQ2d at 1525-26.

Similarly, in *Ball*, the issued claim recited "a plurality of feedlines" and a "substantially cylindrical conductor." 729 F.2d at 1432-33, 221 USPQ at 291-92. The canceled claim recited "feed means includ[ing] at least one conductive lead," and a "substantially cylindrical conductor." The prosecution history showed that the patentee added the "plurality of feedlines" limitation in an effort to overcome prior art, but the cylindrical configuration limitation was neither added in an effort to overcome a prior art rejection, nor argued to distinguish the claims from a reference. *Id.* The reissue claim included limitations not present in the canceled claims that related to the feed means element, but allowed for multiple feedlines. On balance, the claim was narrower than the canceled claim with respect to the feed means aspect. The reissue claim also deleted the cylindrical configuration limitation, which made the claim broader with respect to the configuration of the conductor. *Id.* at 1437, 221 USPQ at 295. We allowed the reissue claim because the patentee was not attempting to recapture surrendered subject matter. *Id.* at 1438, 221 USPQ at 296.

[2,3] In both *Mentor* and *Ball*, the relevance of the prior art rejection to the aspects narrowed in the reissue claim was an important factor in our analysis. From the results and reasoning of those cases, the following principles flow: (1) if the reissue claim is as broad as or broader than the canceled or amended claim in all aspects, the recapture rule bars the claim; (2) if it is narrower in all aspects, the recapture rule does not apply, but other rejections are possible; (3) if the reissue claim is broader in some aspects, but narrower in others, then: (a) if the reissue claim is as broad as or broader in an aspect germane to a prior art rejection, but narrower in another aspect completely unrelated to the rejection, the recapture rule bars the claim; (b) if the reissue claim is narrower in an aspect germane to prior art rejection, and broader in an aspect unrelated to the rejection, the recapture rule does not bar the claim, but other rejections are possible. *Mentor* is an example of (3)(a); *Ball* is an example of (3)(b).

[4] In our case, reissue claim 49 is both broader and narrower in areas relevant to the prior art rejections. Comparing reissue claim 49 with claim 42 before the May 1988 and June 1987, amendments (see the tables at Appendices A and B), we see that claim 49 is narrower in one area, namely, the brightness is "at least 59 ISO in the final pulp." This narrowing relates to a prior art rejection because, during the prosecution of the '179 patent, Clement added this brightness limitation in an effort to overcome Burns. Our comparison also reveals that reissue claim 49

is broader in that it eliminates the room temperature and specific energy limitations of step (a), and the temperature, specific energy, and pH values of steps (c) and (d). This broadening directly relates to several prior art rejections because, in an effort to overcome Ortner, Clement added to step (a) the limitation that it is carried out "at room temperature," and applies "specific mechanical energy lower than 50 KW.H/Ton to form a pumpable slurry. . . ." He argued, moreover, that the latter limitation overcame Burns despite the examiner's contention to the contrary. Clement also added to steps (c) and (d) the temperature and specific energy values in an effort to overcome Ortner, and the "strong" alkaline conditions "having a pH of at least 9" limitation in an effort to overcome Burns. Clement admitted, furthermore, that he added these "very specific process parameters . . . in order to distinguish over the prior art." Claim 49 omits each of these limitations.

On balance, reissue claim 49 is broader than it is narrower in a manner directly pertinent to the subject matter that Clement surrendered throughout the prosecution. Even with the additional limitations, claims 50-52 are also broader than they are narrower in a manner directly pertinent to the subject matter that Clement surrendered during prosecution.

[5] We do not address whether the reissue claims in this case are broader than the canceled claims in a manner directly related to the alleged error supporting reissue because we see no dispositive significance in this inquiry. In *Ball*, we said that the recapture rule does not apply when the reissue claim is broader than the canceled claim in a manner unrelated to the alleged error supporting reissue, but did not address whether the recapture rule would apply if the broadening did relate to the alleged error. 729 F.2d at 1438, 221 USPQ at 296. We can envision a scenario in which the patentee intentionally fails to enumerate an error so that he may eliminate a limitation that he argued distinguished the claim from a reference or added in an effort to overcome a reference and claim protection under *Ball*. We, therefore, think *Ball* is limited to its facts: the recapture rule does not apply when the broadening not only relates to an aspect of the claim that was never narrowed to overcome prior art, or argued as distinguishing the claim from the prior art, but also is not materially related to the alleged error. Accordingly, *Ball* does not require us to determine whether the broader aspects of the reissue claims are related to the alleged error supporting reissue.

Clement argues that, although claim 49 is broader than the issued claims, it is materially narrower than original claim 1; therefore, the recapture rule should not apply. He relies on the unsupported assumption that, for purposes of the recapture rule, we should compare the scope of the reissue claims with that of only original claim 1 to determine whether or not the reissue claim is broader in a material way. Clement has chosen original claim 1 as the basis for comparison because, in his view, it does not include limitations enumerated by the board as missing from the reissue claims. These limitations are the room temperature limitation in step (a) and the specific values of the specific energy limitations in steps (c) and (d).

Clement's assumption ignores the board's finding that the reissue claims delete the value of the high temperature and pH limitations in steps (c) and (d) and the room temperature limitation of step (b). It also ignores much of the prosecution history. The prosecution history shows that Clement abandoned the subject matter of claim 42, as it existed before the examiner's amendment dated May 16, 1988, because he allowed the examiner to amend it to obtain allowance and no other evidence suggests that Clement did not intend to abandon it. He also abandoned the subject matter of claim 42, as it existed before his June 29, 1987, amendment, as it existed before his December 23, 1986, amendment, and as it existed in his preliminary amendment. Based on his actions and statements in the prosecution history of the '179 patent and his admission in the history of the '012 application, every time Clement amended his claims, he intentionally omitted or abandoned the claimed subject matter. Furthermore, his argument that we should compare reissue claim 49 with original claim 1 is reminiscent of the patentee's unsuccessful argument in *Byers*. There, the patentee argued that the reissue claims were "intermediate in scope between certain broad claims which were canceled from [the patentee's] original application and the limited claim allowed in the patent." 230 F.2d at 457, 109 USPQ at 57. In response, the court noted that the "rejection is not based on the cancellation of the broader claims referred to in [the patentee's] brief. . . . The fact that there were other claims whose cancellation did not constitute such a bar is immaterial." *Id.*

We agree with the board's conclusion that the reissue claims are broader than the patent claims in a manner directly pertinent to the subject matter that Clement surrendered during prosecution. Therefore, it correctly applied the recapture rule, and we affirm the

board's decision to sustain the examiner's rejection of claims 49-52.

[6] Because we affirm the board's decision on recapture, Clement cannot cure the allegedly defective declaration with respect to claims 49-52. As a result, we do not reach that issue. Because claims 1-18 are not subject to the recapture rule, however, a defective declaration would not, in and of itself, invalidate them. The Commissioner concedes this point and reminds that, because under 35 U.S.C. § 252 (1994) the surrender of the '179 patent does not take effect until the reissue patent issues, "original claims 1-18 continue to exist with their normal presumption of validity," unaffected by the examiner's rejection based on the allegedly defective declaration. We, therefore, vacate the board's decision to the extent that it rejects claims 1-18 because of the allegedly defective declaration.

Claims 1-18 alone cannot support a reissue application. *See In re Keil*, 808 F.2d 830, 830, 1 USPQ2d 1427, 1428 (Fed. Cir. 1987) (Section 251 requires a change in "either the patent specification or claims."); *In re Dien*, 680 F.2d 151, 152 n.4, 214 USPQ 10, 12 n.4 (CCPA 1982) ("[I]t goes without saying that reissue of a patent in identical form with the original patent is not a possibility."). The '951 application would fail, therefore, to comply with section 251 even if Clement were to cure the allegedly defective declaration.

Conclusion

Accordingly, the decision of the Board of Patent Appeals and Interferences sustaining the rejection of claims 49-52, and to reject the reissue application is affirmed, and its decision to reject original claims 1-18 is vacated.

COSTS

Each party shall bear its own costs.

AFFIRMED IN PART AND VACATED IN PART.

APPENDIX A

Claim 42 Before Clement's Amendment on 6/29/87	**Claim 42 Before Examiner's Amendment on 5/16/88**
A method of treating a mixture of printed and contaminated waste paper in order to produce pulps for use in the manufacture of paper and paperboards, which method comprises:	A method of treating a mixture of printed and contaminated waste paper in order to produce pulps for use in the manufacture of paper and paperboards, which method comprises:
(a) forming an aqueous fibrous suspension of said waste paper at room temperature without deinking agents by applying specific mechanical energy lower that [sic] 50 KW.H/Ton to form a pumpable slurry and to release the non-ink contaminants, from the surface of the paper fibers in the absence of deinking agents and without dispersing such non-ink contaminants as finely divided particles throughout the fibrous suspension;	(a) forming a first aqueous fibrous suspension of said waste paper at room temperature by applying specific mechanical energy lower that [sic] 50 KW.H/Ton to form a pumpable slurry and to release the non-ink contaminants from the surface of the paper and without dispersing such non-ink contaminants as finely divided particles throughout the fibrous suspension;
(b) removing the released non-ink contaminants from the fibrous suspension by screening and cleaning;	(b) removing the non-ink contaminants which have been released without dispersal as finely divided particles from the first fibrous suspension by screening and cleaning to form a second aqueous fibrous suspension substantially free of non-ink contaminants;
(c) softening the ink vehicles and weakening their binding with the surface of the fibers by submitting the fibrous suspension at a consistency of more than 15% to the simultaneous actions of (A) a high temperature between 85° and 130° C,	(c) after the step of removing the non-ink contaminants softening the ink vehicles and weakening their binding with the surface of the fibers by submitting the second fibrous suspension at a consistency of more than 15% to the simultaneous ac-

APPENDIX A

Claim 42 Before Clement's Amendment on 6/29/87	Claim 42 Before Examiner's Amendment on 5/16/88
(B) high shear forces substantially corresponding to a specific mechanical energy of more than 50 KW.H/Ton applied at the said consistency of more than 15% and (C) at least one deinking agent under strong alkaline conditions having a pH preferably greater than 9;	tions of (A) a high temperature between 85° and 130° C, (B) high shear forces substantially corresponding to a specific mechanical energy of more than 50 KW.H/Ton applied at the said consistency of more than 15% and (C) at least one deinking agent under strong alkaline conditions having a pH of at least 9; and
(d) detaching the ink particles from the surface of the fibers and dispersing them into the fibrous suspension by submitting the fibrous suspension to the simultaneous actions of (A) high temperature between 85° and 130° C, (B) high shear forces substantially corresponding to a specific mechanical energy of more than 50 KW.H/Ton applied at the said consistency of more that [sic] 15% and (C) at least one chemical dispersing agent, under strong alkaline conditions having a pH preferably greater than 9;	(d) detaching the ink particles from the surface of the fibers and dispersing them into the second fibrous suspension by submitting the second fibrous suspension to the simultaneous actions of (A) high temperature between 85° and 130° C, (B) high shear forces substantially corresponding to a specific mechanical energy of more that [sic] 50 KW.H/Ton applied at the said consistency of more than 15% and (C) at least one chemical dispersing agent, under strong alkaline conditions having a pH of at least 9 whereby higher specific energy inputs and higher temperatures are used to detach the ink particles from the fibers of the second fibrous suspension after removal of the non-ink contaminants than are used on the first fibrous suspension before removal of the non-ink contaminants;
(e) limiting the total duration of the ink softening and detaching steps (c) and (d) to a range between 2 and 10 minutes and	(e) limiting the total duration of the ink softening and detaching steps (c) and (d) to a range between 2 and 10 minutes and
(f) removing the detached ink particles from the fibrous suspension to provide the degree of brightness required in the final product of the pulp.	(f) removing the detached ink particles from the second fibrous suspension to provide the degree of brightness required in the final product of the pulp.

APPENDIX B

Patent Claim 1	Reissue Claim 49
A method of treating a mixture of printed and contaminated waste paper in order to produce a pulp for use in the manufacture of paper and paperboards, said waste paper containing non-ink contaminants including stickies, which method comprises:	A method of treating a mixture of printed and contaminated waste paper in order to produce a pulp for use in the manufacture of paper and paperboards, said waste paper containing non-ink contaminants including stickies, which method comprises:
(a) forming a first aqueous fibrous suspension of said waste paper at *room temperature* by applying *specific mechanical energy lower that [sic] 50 KW.H/Ton to* form a pumpable slurry and to release substantially all of the non-ink contaminants including the stickies, from the sur-	(a) forming a first aqueous fibrous suspension of said waste paper *at a temperature below the melting point of the non-ink contaminants* by applying *specific mechanical energy sufficient to* form a pumpable slurry and to release substantially all of the non-ink contaminants in-

APPENDIX B

Patent Claim 1	Reissue Claim 49
face of the paper and without dispersing such non-ink contaminants as finely divided particles throughout the fibrous suspension;	cluding the stickies, from the surface of the paper and without dispersing such non-ink contaminants as finely divided particles throughout the fibrous suspension;
(b) removing substantially all of the non-ink contaminants including the stickies, which have been released without dispersal as finely divided particles from the first fibrous suspension by screening and cleaning *at room temperature* to form a second aqueous fibrous suspension substantially free of the non-ink contaminants including the stickies;	(b) removing substantially all of the non-ink contaminants including the stickies, which have been released without dispersal as finely divided particles from the first fibrous suspension by screening and cleaning to form a second aqueous fibrous suspension substantially free of the non-ink contaminants including the stickies;
(c) after the step of removing the non-ink contaminants softening the ink vehicles and weakening their binding with the surface of the fibers by submitting the second fibrous suspension at a consistency of more than 15% to the simultaneous actions of *(A) a high temperature between 85° and 130° C., (B) high shear forces substantially corresponding to a specific mechanical energy of more than 50 KW.H/Ton* applied at the said consistency of more than 15% and *(C) at least one deinking agent under strong alkaline conditions having a pH of at least 9*; and	(c) after the step of removing the non-ink contaminants, *(1)* softening the ink vehicles and weakening their binding with the surface of the fibers, and then *(2)* detaching the ink particles from the surface of the fibers and dispersing the particles into the second fibrous suspension by submitting the second fibrous suspension at a consistency of more than 15% to the simultaneous actions of temperature, pressure, specific energy and chemical dosing sufficient to insure softening of the ink vehicles,
(d) detaching the ink particles from the surface of the fibers and dispersing them into the second fibrous suspension by submitting the second fibrous suspension to the simultaneous actions of *(A) high temperature between 85° and 130° C., (B) high shear forces substantially corresponding to a specific mechanical energy of more than 50 KW.H/Ton* applied at the said consistency of more that [sic] 15% and *(C) at least one chemical dispersing agent, under strong alkaline conditions having a pH of at least 9* whereby higher specific energy inputs and higher temperatures are used to detach the ink particles from the fibers of the second fibrous suspension after removal of the non-ink contaminants than are used on the first fibrous suspension before removal of the non-ink contaminants;	detachment of the ink particles from the surface of the fibers and dispersion of the detached ink particles into the second fibrous suspension, whereby higher specific energy inputs and higher temperatures are used to detach the ink particles from the fibers of the second fibrous suspension after removal of the non-ink contaminants than are used on the first fibrous suspension before removal of the non-ink contaminants;
(e) limiting the total duration of the ink softening and detaching steps (c) and *(d)* to a range between 2 and 10 minutes and	*(d)* limiting the total duration of step (c)*(1)* and *(c)(2)* to a range between 2 and 10 minutes and
(f) removing the detached ink particles from the second fibrous suspension to provide a brightness of at lesat [sic] 59 ISO [in] the final pulp.	*(e)* removing the detached ink particles from the second fibrous suspension to provide a brightness of at least 59 ISO in the final pulp.

APPENDIX B

U.S. Pat. No. 5,210,015 to Gelfand *et al.*

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 5,210,015

DATED : May 11, 1993

INVENTOR(S) : David H. Gelfand, Pamela M. Holland, Randall K. Saiki, and Robert M. Watson

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 3, line 38, please delete "Tag" and insert therefor --Taq--.

Column 4, line 37, please delete "=" and insert therefor --'--.

Column 6, line 14, please delete "Tag" and insert therefor --Taq--.

Column 6, line 18, please delete "Tag" and insert therefor --Taq--.

Column 6, line 20, please delete "Tag" and insert therefor --Taq--.

Column 8, line 39, please delete "Non complementary" and insert therefor --Non-complementary--.

Column 8, lines 43 and 44, please delete "non complementary" and insert therefor --non-complementary--.

Column 8, lines 48 and 49, after "encounters" please insert --this duplex--.

Column 11, line 46, please delete "(Tag)" and insert therefor --(Taq)--.

Column 14, line 10, please delete "Tag" and insert therefor --Taq--.

Column 14, line 29, please delete "Tag" and insert therefor --Taq--.

Column 14, line 35, please delete "Tag" and insert therefor --Taq--.

Column 16, line 42, please delete "Tag" and insert therefor --Taq--.

Column 16, line 47, please delete "Tag" and insert therefor --Taq--.

Column 17, line 51, please delete "Tag" and insert therefor --Taq--.

Column 18, line 52, after "through" please delete "1" and insert therefor --11--.

Column 19, line 61, please delete "Tag" and insert therefor --Taq--.

Column 20, line 42, please delete "Tag" and insert therefor --Taq--.

US005210015A

United States Patent [19]

Gelfand et al.

[11] Patent Number: 5,210,015

[45] Date of Patent: May 11, 1993

[54] **HOMOGENEOUS ASSAY SYSTEM USING THE NUCLEASE ACTIVITY OF A NUCLEIC ACID POLYMERASE**

[75] Inventors: **David H. Gelfand; Pamela M. Holland**, both of Oakland; **Randall K. Saiki**, Richmond; **Robert M. Watson**, Berkeley, all of Calif.

[73] Assignee: **Hoffman-La Roche Inc.**, Nutley, N.J.

[21] Appl. No.: **563,758**

[22] Filed: **Aug. 6, 1990**

[51] **Int. Cl.**[5] **C12Q 1/68; C07H 21/00**

[52] **U.S. Cl.** **435/6**; 435/18; 435/91; 435/196; 435/805; 436/501; 436/63; 436/815; 536/24.3; 935/17; 935/77; 935/78; 935/88

[58] **Field of Search** 435/6, 18, 91, 196, 435/805; 436/501, 63, 815; 536/27; 935/17, 77, 78, 88

[56] **References Cited**

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4,683,195	7/1987	Mullis et al.	435/6
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4,889,818	12/1989	Gelfand et al.	435/194
4,914,210	4/1990	Levenson et al.	548/413
5,011,769	4/1991	Duck et al.	435/6
5,108,892	5/1992	Burke et al.	435/6

FOREIGN PATENT DOCUMENTS

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8909284	10/1989	PCT Int'l Appl. .
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Settow et al. (1972) Journal of Biological Chemistry, vol. 247, No. 1, pp. 224–231.

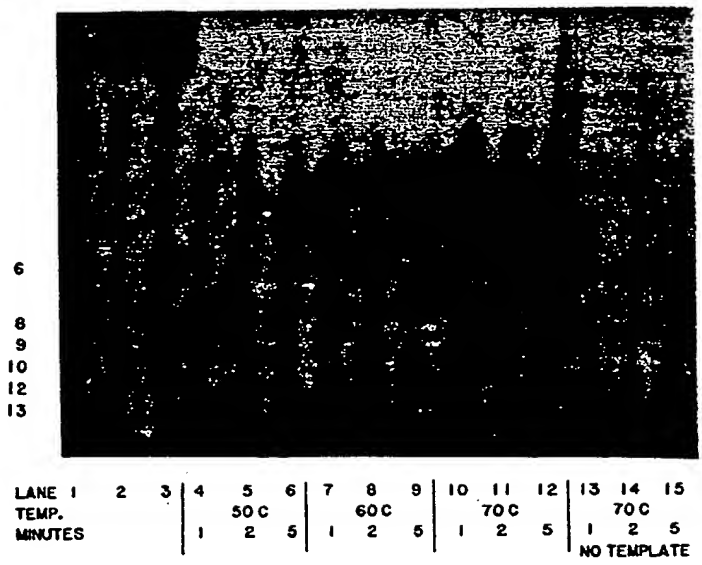
Lehman et al. (1973) Journal of Biological Chemistry, vol. 248, No. 22, pp. 7717–7723.

Primary Examiner—Margaret Moskowitz
Assistant Examiner—Ardin H. Marschel
Attorney, Agent, or Firm—George M. Gould; Dennis P. Tramaloni; Stacev R. Sias

[57] **ABSTRACT**

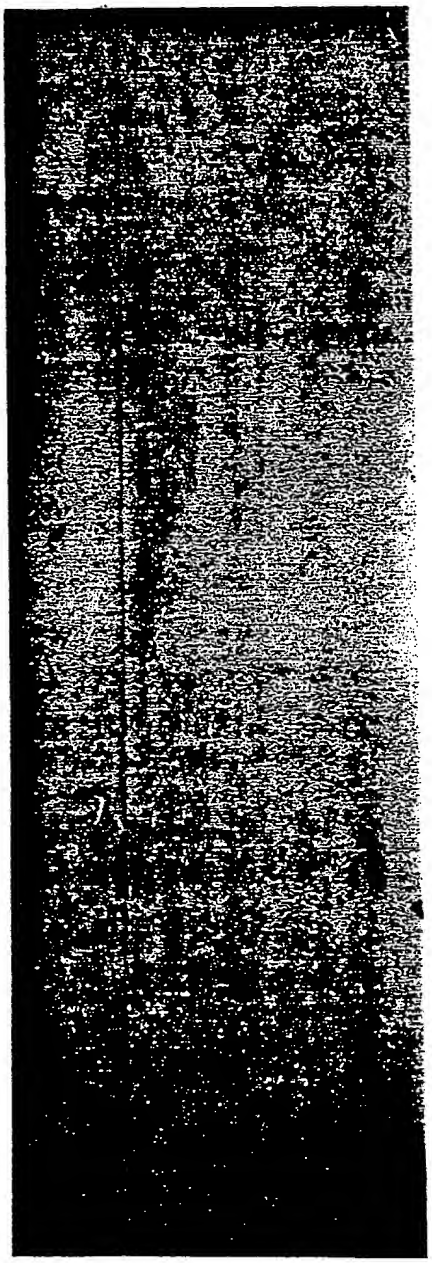
The present invention is directed to a process of detecting a target nucleic acid using labeled oligonucleotides. This process uses the 5' to 3' nuclease activity of a nucleic acid polymerase to cleave annealed labeled oligonucleotide from hybridized duplexes and release labeled oligonucleotide fragments for detection. This process is easily incorporated into a PCR amplification assay.

38 Claims, 10 Drawing Sheets



LANE 1 2 3 4 5 6 7 8 9 10 11 12

FIG. 1



LANE 1 2 3 4 5 6 7 8 9 10 11 12

FIG. 2

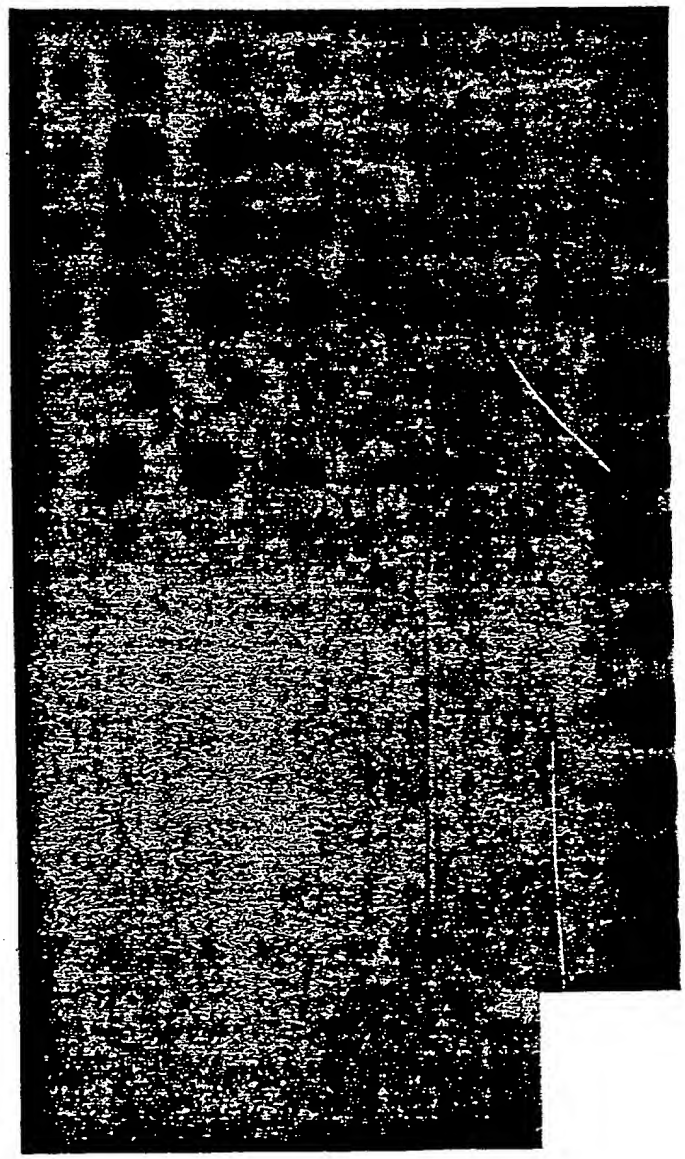


FIG. 3A

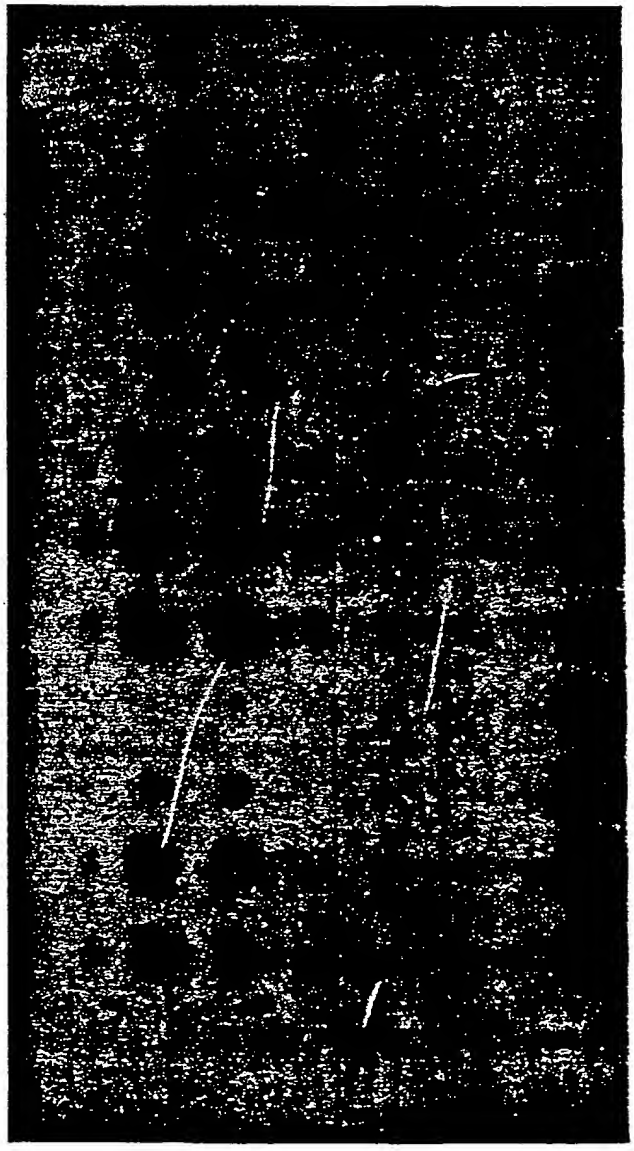


FIG. 3B


LANE 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24
no dNTP
20 uM dNTP
200 uM dNTP
6
8
10
12

FIG. 4

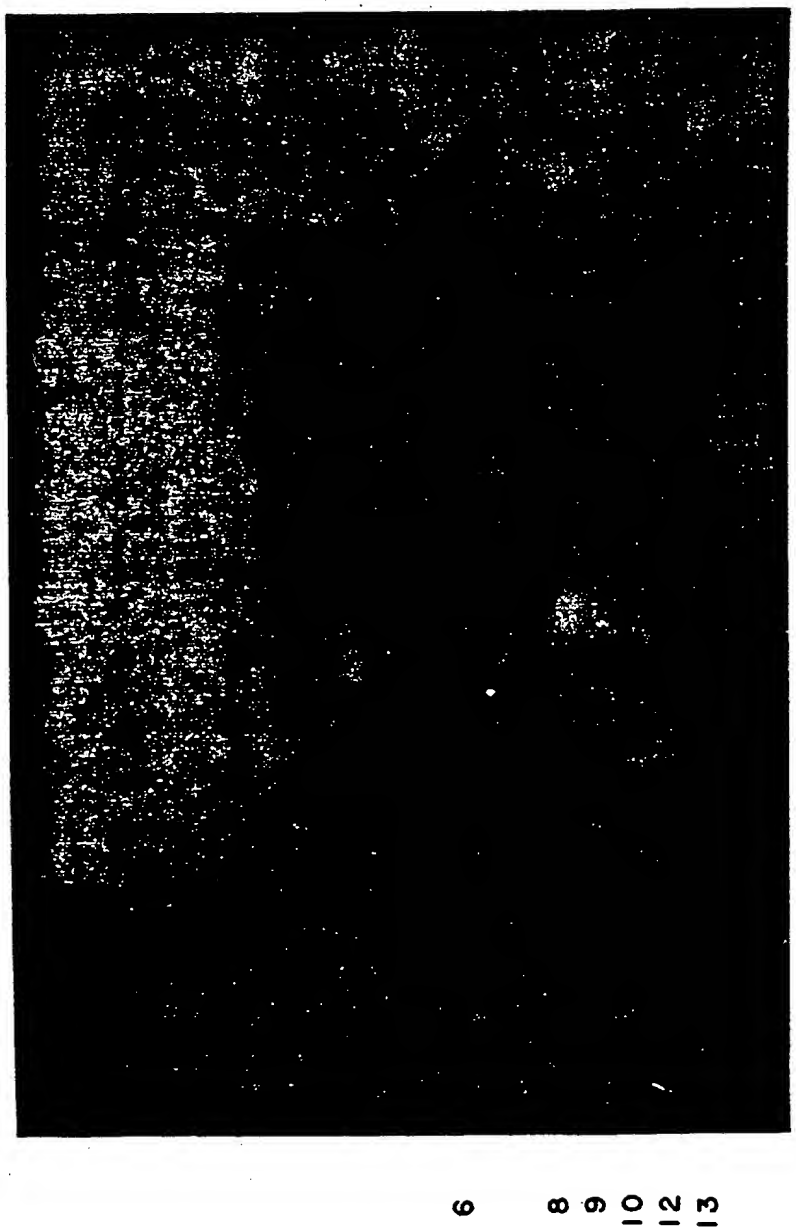

LANE 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15
TEMP. 50C 60C 70C 70C NO TEMPLATE
MINUTES 2 5 1 2 5 1 2 5 1 2 5 1 2 5
6 8 9 10 12 13

FIG. 5

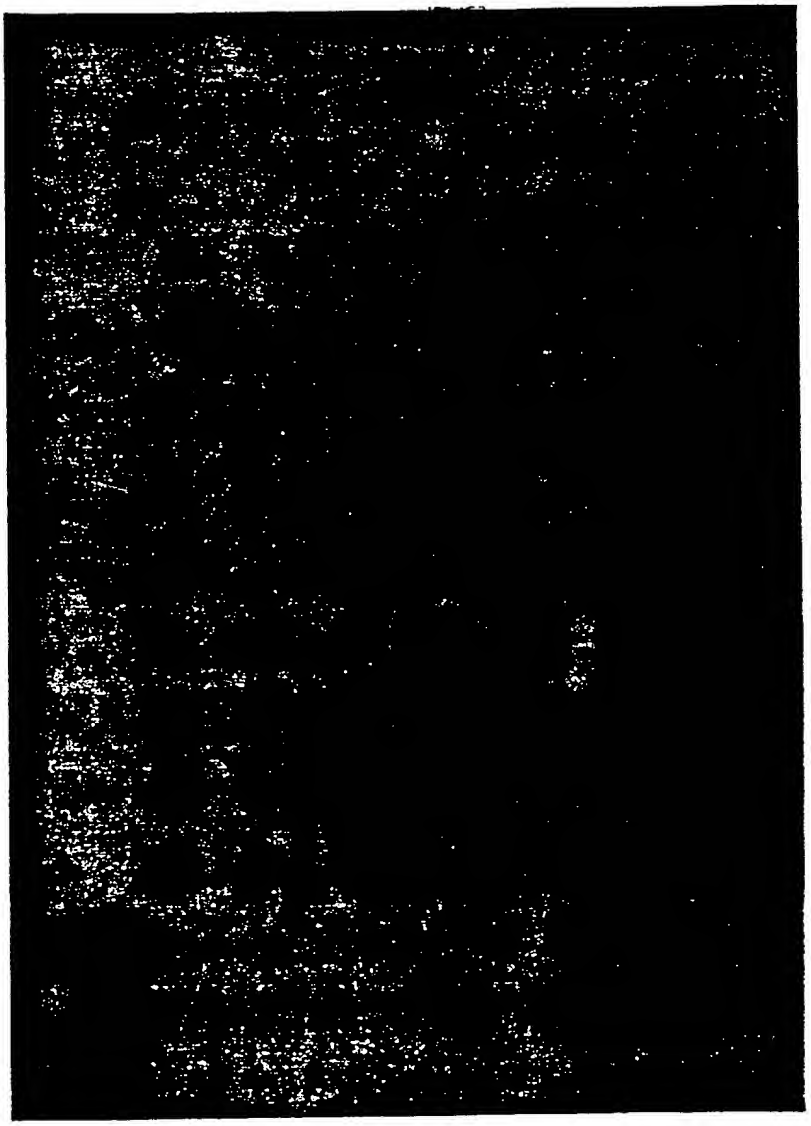

6
8
9
10
12
LANE 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15
TEMP. 50C 60C 70C 70C NO TEMPLATE
MINUTES 1 2 5 1 2 5 1 2 5 1 2 5 1 2 5

FIG. 6

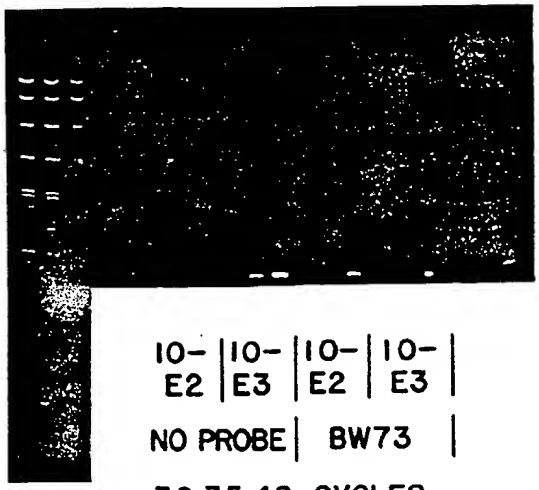

10-E2
10-E3
10-E2
10-E3
NO PROBE
BW73
30,35,40, CYCLES

FIG. 7A

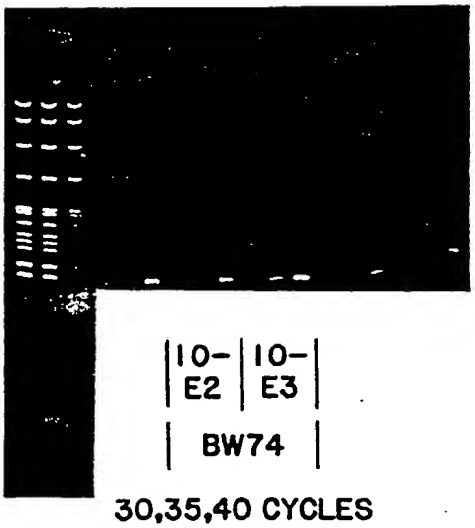

10-E2
10-E3
BW74
30,35,40 CYCLES

FIG. 7B

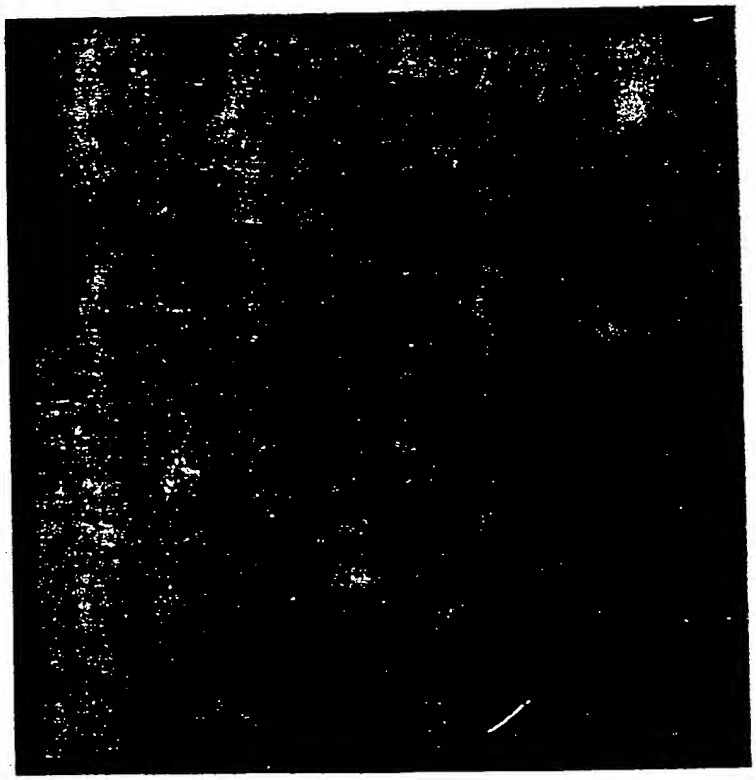
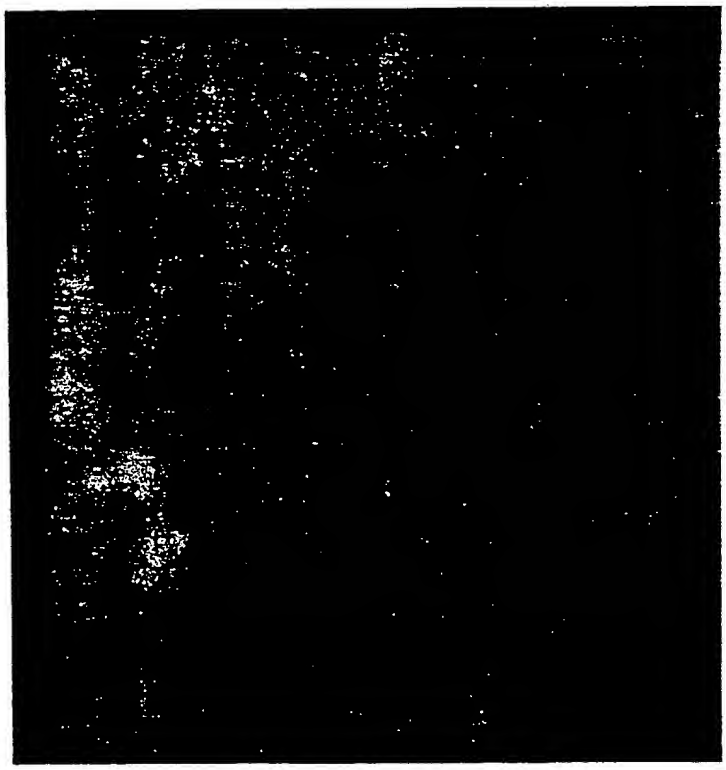


FIG. 8A



1 2 3 4 5 6 7 8 9

FIG. 8B

HOMOGENEOUS ASSAY SYSTEM USING THE NUCLEASE ACTIVITY OF A NUCLEIC ACID POLYMERASE

TECHNICAL FIELD

This invention relates generally to the field of nucleic acid chemistry. More specifically, it relates to the use of the 5' to 3' nuclease activity of a nucleic acid polymerase to degrade a labeled oligonucleotide in a hybridized duplex composed of the labeled oligonucleotide and a target oligonucleotide sequence and form detectable labeled fragments.

BACKGROUND OF THE INVENTION

Investigational microbiological techniques are routinely being applied to diagnostic assays. For example, Falkow et al., U.S. Pat. No. 4,358,535 disclose a method for detecting pathogens by spotting a sample e.g., blood, cells, saliva, etc. on a filter (e.g., nitrocellulose), lysing the cells, and fixing the DNA through chemical denaturation and heating. Then, labeled DNA probes are added and allowed to hybridize with the fixed sample DNA, hybridization indicating the presence of the pathogen's DNA. The sample DNA in this case may be amplified by culturing the cells or organisms in place on the filter.

A significant improvement in DNA amplification, the polymerase chain reaction (PCR) technique, is disclosed in U.S. Pat. Nos. 4,683,202, 4,683,195 and 4,800,159. In its simplest form, PCR is an in vitro method for the enzymatic synthesis of specific DNA sequences, using two oligonucleotide primers that hybridize to opposite strands and flank the region of interest in the target DNA. A repetitive series of reaction steps involving template denaturation, primer annealing, and the extension of the annealed primers by DNA polymerase results in the exponential accumulation of a specific fragment whose termini are defined by the 5' ends of the primers. PCR is reported to be capable of producing a selective enrichment of a specific DNA sequence by a factor of 10^9. The PCR method is also described in Saiki et al., (1985) *Science* 230:1350.

Detection methods generally employed in standard PCR techniques use a labeled probe with the amplified DNA in a hybridization assay. For example, commonly-owned copending patent application U.S. Ser. Nos. 899,344 and 178,276 to Erlich et al., disclose assay methods wherein the PCR-amplified DNA is first fixed to a filter and then a specific oligonucleotide probe is added and allowed to hybridize. Preferably, the probe is labeled, e.g., with ^{32}P, biotin, horseradish peroxidase (HRP), etc., to allow for detection of hybridization. The reverse is also suggested, that is, the probe is instead bound to the membrane and the PCR amplified sample DNA is added.

Other means of detection include the use of fragment length polymorphism (PCR FLP), hybridization to allele-specific oligonucleotide (ASO) probes (Saiki et al., (1986) Nature 324:163), or direct sequencing via the dideoxy method (using amplified DNA rather than cloned DNA). The standard PCR technique operates (essentially) by replicating a DNA sequence positioned between two primers, providing as the major product of the reaction a DNA sequence of discrete length terminating with the primer at the 5' end of each strand. Thus, insertions and deletions between the primers result in product sequences of different lengths, which can be detected by sizing the product in PCR-FLP. In an example of ASO hybridization, the amplified DNA is fixed to a nylon filter (by, for example, UV irradiation) in a series of "dot blots", then allowed to hybridize with an oligonucleotide probe labeled with HRP under stringent conditions. After washing, tetramethylbenzidine (TMB) and hydrogen peroxide are added: HRP oxidizes the hydrogen peroxide which in turn oxidizes the TMB to a blue precipitate, indicating hybridized probe.

While the PCR technique as presently practiced is an extremely powerful method for amplifying nucleic acid sequences, the detection of the amplified material requires additional manipulation and subsequent handling of the PCR products to determine whether the target DNA is present. It would be desirable to decrease the number of subsequent handling steps currently required for the detection of amplified material. A "homogeneous" assay system, that is, one which generates signal while the target sequence is amplified, requiring minimal post amplification handling, would be ideal.

DISCLOSURE OF THE INVENTION

The present invention provides a process for the detection of a target nucleic acid sequence in a sample, said process comprising:

(a) contacting a sample comprising single-stranded nucleic acids with an oligonucleotide containing a sequence complementary to a region of the target nucleic acid and a labeled oligonucleotide containing a sequence complementary to a second region of the same target nucleic acid strand, but not including the nucleic acid sequence defined by the first oligonucleotide, to create a mixture of duplexes during hybridization conditions, wherein the duplexes comprise the target nucleic acid annealed to the first oligonucleotide and to the labeled oligonucleotide such that the 3' end of the first oligonucleotide is adjacent to the 5' end of the labeled oligonucleotide;

(b) maintaining the mixture of step (a) with a template-dependent nucleic acid polymerase having a 5' to 3' nuclease activity under conditions sufficient to permit the 5' to 3' nuclease activity of the polymerase to cleave the annealed, labeled oligonucleotide and release labeled fragments; and

(c) detecting and/or measuring the release of labeled fragments.

This process is especially suited for analysis of nucleic acid amplified by PCR. This process is an improvement over known PCR detection methods because it allows for both amplification of a target and the release of a label for detection to be accomplished in a reaction system without resort to multiple handling steps of the amplified product. Thus, in another embodiment of the invention, a polymerase chain reaction amplification method for concurrent amplification and detection of a target nucleic acid sequence in a sample is provided. This method comprises:

(a) providing to a PCR assay containing said sample, at least one labeled oligonucleotide containing a sequence complementary to a region of the target nucleic acid, wherein said labeled oligonucleotide anneals within the target nucleic acid sequence bounded by the oligonucleotide primers f step (b);

(b) providing a set f oligonucleotide primers, wherein a first primer contains a sequence complementary to a region in one strand of the target nucleic acid sequence and primes the synthesis of a complementary

DNA strand, and a second primer contains a sequence complementary to a region in a second strand of the target nucleic acid sequence and primes the synthesis of a complementary DNA strand; and wherein each oligonucleotide primer is selected to anneal to its complementary template upstream of any labeled oligonucleotide annealed to the same nucleic acid strand;

(c) amplifying the target nucleic acid sequence employing a nucleic acid polymerase having 5' to 3' nuclease activity as a template dependent polymerizing agent under conditions which are permissive for PCR cycling steps of (i) annealing of primers and labeled oligonucleotide to a template nucleic acid sequence contained within the target region, and (ii) extending the primer, wherein said nucleic acid polymerase synthesizes a primer extension product while the 5' to 3' nuclease activity of the nucleic acid polymerase simultaneously releases labeled fragments from the annealed duplexes comprising labeled oligonucleotide and its complementary template nucleic acid sequences, thereby creating detectable labeled fragments; and

(d) detecting and/or measuring the release of labeled fragments to determine the presence or absence of target sequence in the sample.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is an autoradiograph of a DEAE cellulose thin layer chromatography (TLC) plate illustrating the release of labeled fragments from cleaved probe.

FIG. 2 is an autoradiograph of DEAE cellulose TLC plates illustrating the thermostability of the labeled probe.

FIGS. 3A and 3B are autoradiographs of DEAE cellulose TLC plates showing that the amount of labeled probe fragment released correlates with an increase in PCR cycle number and starting template DNA concentration.

FIG. 4 illustrates the polymerization independent 5'-3' nuclease activity of Tag DNA polymerase shown in the autoradiograph using a series of primers which anneal from zero to 20 nucleotides upstream of the probe.

FIG. 5 is an autoradiograph showing the release of labeled probe fragments under increasing incubation temperatures and time, wherein the composition at the 5' end of the probe is GC rich.

FIG. 6 is an autoradiograph showing the release of labeled probe fragments under increasing incubation temperatures and time, wherein the composition at the 5' end of the probe is AT rich.

FIG. 7A and 7B provides 5% acrylamide electrophoresis gel analysis of a 142 base pair HIV product, amplified in the presence or absence of labeled probe.

FIG. 8A and 8B are autoradiographs of TLC analysis of aliquots of PCR amplification products which show that radiolabel release occurs and increases in amount with both increases in starting template and with longer thermocycling.

MODES OF CARRYING OUT THE INVENTION

A. Definitions

As used herein, a "sample" refers to a sample of tissue or fluid isolated from an individual or individuals, including but not limited to, for example, skin, plasma, serum, spinal fluid, lymph fluid, synovial fluid, urine, tears, blood cells, rgans, tumors, and also to samples of in vitro cell culture constituents (including but not limited to conditioned medium resulting from the growth of cells in cell culture medium, recombinant cells and cell components).

As used herein, the terms "nucleic acid", "polynucleotide" and "oligonucleotide" refer to primers, probes, oligomer fragments to be detected, oligomer controls and unlabeled blocking oligomers and shall be generic to polydeoxyribonucleotides (containing 2-deoxy-D-ribose), to polyribonucleotides (containing D-ribose), and to any other type of polynucleotide which is an N glycoside of a purine or pyrimidine base, or modified purine or pyrimidine bases. There is no intended distinction in length between the term "nucleic acid", "polynucleotide" and "oligonucleotide", and these terms will be used interchangeably. These terms refer only to the primary structure of the molecule. Thus, these terms include double- and single-stranded DNA, as well as double- and single stranded RNA. The oligonucleotide is comprised of a sequence of approximately at least 6 nucleotides, preferably at least about 10-12 nucleotides, and more preferably at least about 15-20 nucleotides corresponding to a region of the designated nucleotide sequence. "Corresponding" means identical to or complementary to the designated sequence.

The oligonucleotide is not necessarily physically derived from any existing or natural sequence but may be generated in any manner, including chemical synthesis, DNA replication, reverse transcription or a combination thereof. The terms "oligonucleotide" or "nucleic acid" intend a polynucleotide of genomic DNA or RNA, cDNA, semisynthetic, or synthetic origin which, by virtue of its origin or manipulation: (1) is not associated with all or a portion of the polynucleotide with which it is associated in nature; and/or (2) is linked to a polynucleotide other than that to which it is linked in nature; and (3) is not found in nature.

Because mononucleotides are reacted to make oligonucleotides in a manner such that the 5= phosphate of one mononucleotide pentose ring is attached to the 3' oxygen of its neighbor in one direction via a phosphodiester linkage, an end of an oligonucleotide is referred to as the "5' end" if its 5' phosphate is not linked to the 3' oxygen of a mononucleotide pentose ring and as the "3' end" if its 3' oxygen is not linked to a 5' phosphate of a subsequent mononucleotide pentose ring. As used herein, a nucleic acid sequence, even if internal to a larger oligonucleotide, also may be said to have a 5' and 3' ends.

When two different, non-overlapping oligonucleotides anneal to different regions of the same linear complementary nucleic acid sequence, the 3' end of one oligonucleotide points toward the 5' end of the other; the former may be called the "upstream" oligonucleotide and the latter the "downstream" oligonucleotide.

The term "primer" may refer to more than one primer and refers to an oligonucleotide, whether occurring naturally, as in a purified restriction digest, or produced synthetically, which is capable of acting as a point of initiation of synthesis along a complementary strand when placed under conditions in which synthesis of a primer extension product which is complementary to a nucleic acid strand is catalyzed. Such conditions include the presence of four different deoxyribonucleoside triphosphates and a polymerization-inducing agent such as DNA polymerase or reverse transcriptase, in a suitable buffer ("buffer" includes substituents which are cofactors, or which affect pH, ionic strength, etc.), and

at a suitable temperature. The primer is preferably single-stranded for maximum efficiency in amplification.

The complement of a nucleic acid sequence as used herein refers to an oligonucleotide which, when aligned with the nucleic acid sequence such that the 5' end of one sequence is paired with the 3' end of the other, is in "antiparallel association." Certain bases not commonly found in natural nucleic acids may be included in the nucleic acids of the present invention include, for example, inosine and 7-deazaguanine. Complementarity need not be perfect; stable duplexes may contain mismatched base pairs or unmatched bases. Those skilled in the art of nucleic acid technology can determine duplex stability empirically considering a number of variables including, for example, the length of the oligonucleotide, percent concentration of cytosine and guanine bases in the oligonucleotide, ionic strength, and incidence of mismatched base pairs.

Stability of a nucleic acid duplex is measured by the melting temperature, or "T_m." The T_m of a particular nucleic acid duplex under specified conditions is the temperature at which half of the base pairs have disassociated.

As used herein, the term "target sequence" or "target nucleic acid sequence" refers to a region of the oligonucleotide which is to be either amplified, detected or both. The target sequence resides between the two primer sequences used for amplification.

As used herein, the term "probe" refers to a labeled oligonucleotide which forms a duplex structure with a sequence in the target nucleic acid, due to complementarity of at least one sequence in the probe with a sequence in the target region. The probe, preferably, does not contain a sequence complementary to sequence(s) used to prime the polymerase chain reaction. Generally the 3' terminus of the probe will be "blocked" to prohibit incorporation of the probe into a primer extension product. "Blocking" may be achieved by using non-complementary bases or by adding a chemical moiety such as biotin or even a phosphate group to the 3' hydroxyl of the last nucleotide, which may, depending upon the selected moiety, may serve a dual purpose by also acting as a label.

The term "label" as used herein refers to any atom or molecule which can be used to provide a detectable (preferably quantifiable) signal, and which can be attached to a nucleic acid or protein. Labels may provide signals detectable by fluorescence, radioactivity, colorimetric, X-ray diffraction or absorption, magnetism, enzymatic activity, and the like.

As defined herein, "5'→3' nuclease activity" or "5' to 3' nuclease activity" refers to that activity of a template-specific nucleic acid polymerase including either a 5'→3' exonuclease activity traditionally associated with some DNA polymerases whereby nucleotides are removed from the 5' end of an oligonucleotide in a sequential manner, (i.e., *E. coli* DNA polymerase I has this activity whereas the Klenow fragment does not), or a 5'→3" endonuclease activity wherein cleavage occurs more than one nucleotide from the 5' end, or both.

By "adjacent" as used herein refers to the positioning of the primer with respect to the probe on its complementary strand of the template nucleic acid. The primer and probe may be separated by 1 to about 20 nucleotides, more preferably, about 1 to 10 nucleotides, or may directly abut one another, as may be desirable for detection with a polymerization-independent process. Alternatively, for use in PCR amplification and detection methods as taught herein, the "adjacency" may be anywhere within the sequence to be amplified.

As used herein, the term "thermostable nucleic acid polymerase" refers to an enzyme which is relatively stable to heat when compared, for example, to nucleotide polymerases from *E. coli* and which catalyzes the polymerization of nucleosides. Generally, the enzyme will initiate synthesis at the 3'-end of the primer annealed to the target sequence, and will proceed in the 5'-direction along the template, and if possessing a 5' to 3' nuclease activity, hydrolyzing intervening, annealed probe to release both labeled and unlabeled probe fragments, until synthesis terminates. A representative thermostable enzyme isolated from *Thermus aquaticus* (Tag) is described in U.S. Pat. No. 4,889,818 and a method for using it in conventional PCR is described in Saiki et al., (1988), *Science* 239:487.

Tag DNA polymerase has a DNA synthesis-dependent, strand replacement 5'-3' exonuclease activity (see Gelfand, "Tag DNA Polymerase" in *PCR Technology: Principles and Applications for DNA Amplification*, Erlich, Ed., Stockton Press, N.Y. (1989), Chapter 2). In solution, there is little, if any, degradation of labeled oligonucleotides.

B. General Method

The practice of the present invention will employ, unless otherwise indicated, conventional techniques of molecular biology, microbiology and recombinant DNA techniques, which are within the skill of the art. Such techniques are explained fully in the literature. See, e.g., Sambrook, Frtisch & Maniatis, *Molecular Cloning: A Laboratory Manual*, Second Edition (1989); *Oligonucleotide Synthesis* (M.J. Gait, ed., 1984); *Nucleic Acid Hybridization* (B.D Hames & S.J. Higgins, eds., 1984); *A Practical Guide to Molecular Cloning* (B. Perbal, 1984); and a series, *Methods in Enzymology* (Academic Press, Inc.). All patents, patent applications, and publications mentioned herein, both supra and infra, are hereby incorporated by reference.

The various aspects of the invention are based on a special property of nucleic acid polymerases. Nucleic acid polymerases are known to possess several activities, among them, a 5' to 3' nuclease activity whereby the nucleic acid polymerase can cleave mononucleotides or small oligonucleotides from an oligonucleotide annealed to its larger, complementary polynucleotide. In order for cleavage to occur, an upstream oligonucleotide must also be annealed to the same larger polynucleotide.

The 3' end of this upstream oligonucleotide provides the initial binding site for the nucleic acid polymerase. As soon as the bound polymerase encounters the 5' end of the downstream oligonucleotide, the polymerase can cleave mononucleotides or small oligonucleotides therefrom.

The two oligonucleotides can be designed such that they anneal in close proximity on the complementary target nucleic acid such that binding of the nucleic acid polymerase to the 3' end of the upstream oligonucleotide automatically puts it in contact with the 5' end of the downstream oligonucleotide. In this process, polymerization is not required to bring the nucleic acid polymerase into position to accomplish the cleavage, therefore we call this polymerization-independent cleavage.

Alternatively, if the two oligonucleotides anneal to more distantly spaced regions of the template nucleic

acid target, polymerization must occur before the nucleic acid polymerase encounters the 5' end of the downstream oligonucleotide. As the polymerization continues, the polymerase progressively cleaves mononucleotides or small oligonucleotides from the 5' end of the downstream oligonucleotide. This cleaving continues until the remainder of the downstream oligonucleotide has been destabilized to the extent that it dissociates from the template molecule. We call this process polymerization-dependent cleavage.

In the present invention, a label is attached to the downstream oligonucleotide. Thus, the cleaved mononucleotides or small oligonucleotides which are cleaved by the 5'-3' nuclease activity of the polymerase can be detected.

Subsequently, any of several strategies may be employed to distinguish the uncleaved labeled oligonucleotide from the cleaved fragments thereof. In this manner, the present invention permits identification of those nucleic acid samples which contain sequences complementary to the upstream and downstream oligonucleotides.

The present invention exploits this 5' to 3' nuclease activity of the polymerase when used in conjunction with PCR. This differs from previously described PCR amplification wherein the post-PCR amplified target oligonucleotides are detected, for example, by hybridization with a probe which forms a stable duplex with that of the target sequence under stringent to moderately stringent hybridization and wash conditions. In contrast to those known detection methods used in post-PCR amplifications, the present invention permits the detection of the target nucleic acid sequences during amplification of this target nucleic acid. In the present invention, a labeled oligonucleotide is added concomitantly with the primer at the start of PCR, and the signal generated from hydrolysis of the labeled nucleotide(s) of the probe provides a means for detection of the target sequence during its amplification.

One advantage of the polymerization-independent process lies in the elimination of the need for amplification of the target sequence. In the absence of primer extension, the target nucleic acid is substantially single-stranded. Provided the primer and labeled oligonucleotide are adjacently bound to the target nucleic acid, sequential rounds of oligonucleotide annealing and cleavage of labeled fragments can occur. Thus, a sufficient amount of labeled fragments can be generated, making detection possible in the absence of polymerization. As would be appreciated by those skilled in the art, the signal generated during PCR amplification could be augmented by this polymerization-independent activity.

In either process described herein, a sample is provided which is suspected of containing the particular oligonucleotide sequence of interest, the "target nucleic acid". The target nucleic acid contained in the sample may be first reverse transcribed into cDNA, if necessary, and then denatured, using any suitable denaturing method, including physical, chemical, or enzymatic means, which are known to those of skill in the art. A preferred physical means for strand separation involves heating the nucleic acid until it is completely (>99%) denatured. Typical heat denaturation involves temperatures ranging fr m about 80° C. to about 105° C., for times ranging from about 1 to 10 minutes. As an alternative to denaturation, the target nucleic acid may exist in a single-stranded form in the sample, such as, for example, single stranded RNA or DNA viruses.

The denatured nucleic acid strands are then incubated with preselected oligonucleotide primers and labeled oligonucleotide (also referred to herein as "probe") under hybridization conditions, conditions which enable the binding of the primers and probes to the single nucleic acid strands. As known in the art, the primers are selected so that their relative positions along a duplex sequence are such that an extension product synthesized from one primer, when the extension product is separated from its template (complement), serves as a template for the extension of the other primer to yield a replicate chain of defined length.

Because the complementary strands are longer than either the probe or primer, the strands have more points of contact and thus a greater chance of finding each other over any given period of time. A high molar excess of probe, plus the primer, helps tip the balance toward primer and probe annealing rather than template reannealing.

The primer must be sufficiently long to prime the synthesis of extension products in the presence of the agent for polymerization. The exact length and composition of the primer will depend on many factors, including temperature of the annealing reaction, source and composition of the primer, proximity of the probe annealing site to the primer annealing site, and ratio of primer:probe concentration. For example, depending on the complexity of the target sequence, the oligonucleotide primer typically contains about 15-30 nucleotides, although it may contain more or fewer nucleotides. The primers must be sufficiently complementary to selectively anneal to their respective strands and form stable duplexes.

The primers used herein are selected to be "substantially" complementary to the different strands of each specific sequence to be amplified. The primers need not reflect the exact sequence of the template, but must be sufficiently complementary to selectively hybridize to their respective strands. Non complementary bases or longer sequences can be interspersed into the primer or located at the ends of the primer, provided the primer retains sufficient complementarity with its template strand to form a stable duplex therewith. The non complementary nucleotide sequences of the primers may include restriction enzyme sites.

In the practice of the invention, the labeled oligonucleotide must be first annealed to its complementary nucleic acid before the nucleic acid polymerase encounters

region, thereby permitting the 5' to 3' nuclease activity to cleave and release labeled oligonucleotide fragments.

To enhance the likelihood that the labeled oligonucleotide will have annealed to its complementary nucleic acid before primer extension polymerization reaches this duplex region, or before the polymerase attaches to the upstream oligonucleotide in the polymerization-independent process, a variety of techniques may be employed. Short primer molecules generally require cooler temperature to form sufficiently stable hybrid complexes with the target nucleic acid. Therefore, the labeled oligonucleotide can be designed to be longer than the primer so that the labeled oligonucleotide anneals preferentially to the target at higher temperatures relative to primer annealing.

One can also use primers and labeled oligonucleotides having differential thermal stability. For example, the nucleotide composition of the labeled oligonucleotide

can be chosen to have greater G/C content and, consequently, greater thermal stability than the primer. The thermocycling parameters can also be varied to take advantage of the differential thermal stability of the labeled oligonucleotide and primer. For example, following the denaturation step in thermocycling, an intermediate temperature may be introduced which is permissible for labeled oligonucleotide binding but not primer binding, and then the temperature is further reduced to permit primer annealing and extension.

To preferentially favor binding of the labeled oligonucleotide before the primer, a high molar excess of labeled oligonucleotide to primer concentration can also be used. Such labeled oligonucleotide concentrations are typically in the range of about 2 to 20 times higher than the respective primer concentration, which is generally $0.5-5\times10^{-7}$ M.

The oligonucleotide primers and labeled oligonucleotides may be prepared by any suitable method. Methods for preparing oligonucleotides of specific sequence are known in the art, and include, for example, cloning and restriction of appropriate sequences, and direct chemical synthesis. Chemical synthesis methods may include, for example, the phosphotriester method described by Narang et al. (1979) *Methods in Enzymology* 68:90, the phosphodiester method disclosed by Brown et al. (1979) *Methods in Enzymology* 68:109, the diethylphosphoramidate method disclosed in Beaucage et al. (1981) *Tetrahedron Letters* 22:1859, and the solid support method disclosed in U.S. Pat. No. 4,458,066.

The composition of the labeled oligonucleotide can be designed to favor nuclease activity over strand displacement (mono- and dinucleotide fragments over oligonucleotides) by means of choice of sequences which are GC rich or which avoid sequential A's and T's and by choice of label position in the probe. It has been determined that in the presence of AT rich sequences in the 5' complementary probe region, cleavage occurs after the approximately fourth, fifth or sixth nucleotide. However, in a GC-rich 5' complementary probe region, cleavage generally occurs after the first or second nucleotide. Alternatively, the incorporation of modified phosphodiester linkages (e.g., methyl phosphorylthioate or methylphosphonates) in the labeled probe during chemical synthesis (Noble et al., (1984) *Nuc Acids Res* 12:3387–3403; Iyer et al., (1990) *J Am Chem Soc* 112:1253–1254) may be used to prevent cleavage at a selected site. Depending on the length of the probe, the composition of its 5' complementary region, and the position of the label, one can design a probe to preferentially favor the generation of short or long labeled probe fragments for use in the practice of the invention.

The oligonucleotide is labeled, as described below, by incorporating moieties detectable by spectroscopic, photochemical, biochemical, immunochemical, or chemical means. The method of linking or conjugating the label to the oligonucleotide probe depends, of course, on the type of label(s) used and the position of the label on the probe.

A variety of labels which would be appropriate for use in the invention, as well as methods for their inclusion in the probe, are known in the art and include, but are not limited to, enzymes (e.g., alkaline phosphatase and horseradish peroxidase) and enzyme substrates, radioactive atoms, fluorescent dyes, chromophores, chemiluminescent labels, electrochemiluminescent labels, such as Origin™ (Igen), ligands having specific binding partners, or any other labels that may interact with each other to enhance, alter, or diminish a signal. Of course, should the PCR be practiced using a Thermo Cycler instrument, the label must be able to survive the temperature cycling required in this automated process.

Among radioactive atoms, ^{32}P is preferred. Methods for introducing ^{32}P into nucleic acids are known in the art, and include, for example, 5' labeling with a kinase, or random insertion by nick translation. Enzymes are typically detected by their activity. "Specific binding partner" refers to a protein capable of binding a ligand molecule with high specificity, as for example in the case of an antigen and a monoclonal antibody specific therefor. Other specific binding partners include biotin and avidin or streptavidin, IgG and protein A, and the numerous receptor-ligand couples known in the art. It should be understood that the above description is not meant to categorize the various labels into distinct classes, as the same label may serve in several different modes. For example, ^{125}I may serve as a radioactive label or as an electron-dense reagent. HRP may serve as enzyme or as antigen for a monoclonal antibody. Further, one may combine various labels for desired effect. For example, one might label a probe with biotin, and detect its presence with avidin labeled with ^{125}I, or with an anti-biotin monoclonal antibody labeled with HRP. Other permutations and possibilities will be readily apparent to those of ordinary skill in the art, and are considered as equivalents within the scope of the instant invention.

In some situations it may be desirable to use two interactive labels on a single oligonucleotide with due consideration given for maintaining an appropriate spacing of the labels on the oligonucleotide to permit the separation of the labels during oligonucleotide hydrolysis, and in other instances it may be desirable to use a single probe having two different label moieties. In this embodiment of the invention, detection of the hydrolyzed labeled probe can be accomplished using, for example, fluorescence polarization. This technique is able to differentiate between large and small molecules based on molecular tumbling. Large molecules (e.g., intact labeled probe) tumble in solution much more slowly than small molecules. Upon linkage of a fluorescent moiety to the molecule of interest (e.g., the 5' end of a labeled probe), this fluorescent moiety can be measured (and differentiated) based on molecular tumbling, thus differentiating between intact and digested probe. Detection may be measured directly during PCR or may be performed post PCR.

In yet another embodiment, two labelled oligonucleotides are used, each complementary to separate regions of a double-stranded target region, but not to each other, oligonucleotide designed to anneal downstream of its respective primer. For example, the presence of two probes can potentially double the intensity of the signal generated from a single label and may further serve to reduce product strand reannealing, as often occurs during PCR amplification. The probes are selected so that their relative positions are adjacent to their respective primers.

The labels may be attached to the oligonucleotide directly or indirectly by a variety of techniques. Depending on the precise type of label used, the label might be located at the 5' or 3' end of the pr be, located internally in the probe's nucleotide sequence, or attached to spacer arms of various sizes and compositions to facilitate signal interactions. Using commercially

available phosphoramidite reagents, one can produce oligomers containing functional groups (e.g., thiols or primary amines) at either terminus via an appropriately protected phosphoramidite, and can label them using protocols described in, for example, *PCR Protocols: A Guide to Methods and Applications*, ed. by Innis et al., Academic Press, Inc., 1990.

Methods for introducing oligonucleotide functionalizing reagents to introduce one or more sulfhydryl, amino or hydroxyl moieties into the oligonucleotide probe sequence, typically at the 5' terminus are described in U.S. Pat. No. 4,914,210. A 5' phosphate group can be introduced as a radioisotope by using polynucleotide kinase and [gamma^{32}P]ATP to provide a reporter group. Biotin can be added to the 5' end by reacting an aminothymidine residue, introduced during synthesis, with an N-hydroxysuccinimide ester of biotin.

Labels at the 3' terminus may employ polynucleotide terminal transferase to add the desired moiety, such as for example, cordycepin ^{35}S-dATP, and biotinylated dUTP.

Oligonucleotide derivatives are also available labels. For example, etheno-dA and etheno-A are known fluorescent adenine nucleotides which can be incorporated into an oligonucleotide probe. Similarly, etheno-dC is another analog that could be used in probe synthesis. The probes containing such nucleotide derivatives may be hydrolyzed to release much more strongly fluorescent mononucleotides by the polymerase's 5' to 3' nuclease activity as DNA polymerase extends a primer during PCR.

Template-dependent extension of the oligonucleotide primer(s) is catalyzed by a polymerizing agent in the presence of adequate amounts of the four deoxyribonucleoside triphosphates (dATP, dGTP, dCTP, and dTTP) or analogs as discussed above, in a reaction medium which is comprised of the appropriate salts, metal cations, and pH buffering system. Suitable polymerizing agents are enzymes known to catalyze primer and template-dependent DNA synthesis and possess the 5' to 3' nuclease activity. Known DNA polymerases include, for example, *E. coli* DNA polymerase I, *Thermus thermophilus* (Tth) DNA polymerase, *Bacillus stearothermophilus* DNA polymerase, *Thermococcus littoralis* DNA polymerase, and *Thermus aquaticus* (Tag) DNA polymerase. The reaction conditions for catalyzing DNA synthesis with these DNA polymerases are well known in the art. To be useful in the present invention, the polymerizing agent must efficiently cleave the oligonucleotide and release labeled fragments so that the signal is directly or indirectly generated.

The products of the synthesis are duplex molecules consisting of the template strands and the primer extension strands, which include the target sequence. By-products of this synthesis are labeled oligonucleotide fragments which consist of a mixture of mono-, di- and larger nucleotide fragments. Repeated cycles of denaturation, labeled oligonucleotide and primer annealing, and primer extension and cleavage of the labeled oligonucleotide result in the exponential accumulation of the target region defined by the primers and the exponential generation of labeled fragments. Sufficient cycles are run to achieve a detectable species of label, which is generally several orders of magnitude greater than background signal.

In a preferred method, the PCR reaction is carried ut as an automated process which utilizes a thermostable enzyme. In this process the reaction mixture is cycled through a denaturing step, a probe and primer annealing step, and a synthesis step, whereby cleavage and displacement occurs simultaneously with primer dependent template extension. A DNA thermal cycler, such as the commercially available machine from Perkin-Elmer Cetus Instruments, which is specifically designed for use with a thermostable enzyme, may be employed.

Temperature stable polymerases are preferred in this automated process because the preferred way of denaturing the double stranded extension products is by exposing them to a high temperature (about 95° C.) during the PCR cycle. For example, U.S. Pat. No. 4,889,818 discloses a representative thermostable enzyme isolated from *Thermus aquaticus*. Additional representative temperature stable polymerases include, e.g., polymerases extracted from the thermostable bacteria *Thermus flavus*, *Thermus ruber*, *Thermus thermophilus*, *Bacillus stearothermophilus* (which has a somewhat lower temperature optimum than the others listed), *Thermus lacteus*, *Thermus rubens*, *Thermotoga maritima*, *Thermococcus littoralis*, and *Methanothermus fervidus*.

Detection or verification of the labeled oligonucleotide fragments may be accomplished by a variety of methods and may be dependent on the source of the label or labels employed. One convenient embodiment of the invention is to subject the reaction products, including the cleaved label fragments to size analysis. Methods for determining the size of the labeled nucleic acid fragments are known in the art, and include, for example, gel electrophoresis, sedimentation in gradients, gel exclusion chromatography and homochromatography.

During or after amplification, separation of the labeled fragments from the PCR mixture can be accomplished by, for example, contacting the PCR mixture with a solid phase extractant (SPE). For example, materials having an ability to bind oligonucleotides on the basis of size, charge or interaction with the oligonucleotide bases can be added to the PCR mixture, under conditions where labeled, uncleaved oligonucleotides are bound and labeled fragments are not. Such SPE materials include ion exchange resins or beads, such as the commercially available binding particles Nensorb TM (DuPont Chemical Co. , Nucleogen TM (The Nest Group) and hydroxylapatite. In a specific embodiment, if a dual labeled oligonucleotide comprising a 3' biotin label separated from a 5' label by a nuclease susceptible cleavage site is employed as the signal means, the PCR amplified mixture can be contacted with materials containing a specific binding partner such as avidin or streptavidin, or an antibody or monoclonal antibody to biotin. Such materials can include beads and particles coated with specific binding partners and can also include magnetic particles.

Following the step wherein the PCR mixture has been contacted with a SPE, the SPE material can be removed by filtration, sedimentation or magnetic attraction leaving the labeled fragments free of uncleaved labeled oligonucleotides and available for detection.

Reagents employed in the methods of the invention can be packaged into diagnostic kits. Diagnostic kits include the labeled oligonucleotides and the primers in separate containers. If the oligonucleotide is unlabeled, the specific labeling reagents may also be included in the kit. The kit may also contain other suitably pack-

aged reagents and materials needed for amplification, for example, buffers, dNTPs, and/or polymerizing means, and for detection analysis, for example, enzymes and solid phase extractants, as well as instructions for conducting the assay.

EXAMPLES

The examples presented below are intended to be illustrative of the various methods and compounds of the invention.

Example I: PCR Probe Label Release

A PCR amplification was performed which liberated the 5' ^{32}P-labeled end of a complementary probe when specific intended product was synthesized.

A Labeling of probe with gamma ^{32}P-ATP and polynucleotide kinase

Ten pmol of each probe (BW31, BW33, BW35, sequences provided below) were individually mixed with fifteen units of T4 polynucleotide kinase (New England Biolabs) and 15.3 pmol of gamma ^{32}P-ATP (New England Nuclear, 3000 Ci/mmol) in a 50 ul reaction volume containing 50 mM Tris HCl, pH 7.5, 10 mM $MgCl_2$, 5 mM dithiothreitol, 0.1 mM spermidine and 0.1 mM EDTA for 60 min at 37° C. The total volume was then phenol/chloroform extracted, and ethanol precipitated as described by Sambrook, et al., *Molecular Cloning*, Second Edition (1989). Probes were resuspended in 100 ul TE buffer and run over a Sephadex G-50 spin dialysis column to remove unincorporated gamma ^{32}P-ATP as taught in Sambrook et al., supra. TCA precipitation of the reaction products indicated the following specific activities:

BW31: 1.98×10^6 cpm/pmol

BW33: 2.54×10^6 cpm/pmol

BW35: 1.77×10^6 cpm/pmol

Final concentration of all three probes was 0.10 pmol/ul.

B. Amplification

The amplified region was a 350 base pair product from the bacteriophage M13mp10w directed by primers BW36 and BW42. The region of each numbered primer sequence designated herein, follows standard M13 nucleotide sequence usage.

BW36 =
5' 5241-5268 3'
5'-CCGATAGTTTGAGTTCTTCTACTCAGGC-3'

-continued

BW42 =
5' 5591-5562 3'
5'-GAAGAAAGCGAAAGGAGCGGGCGCTAGGGC-3'

Three different probes were used, which contained the exact 30 base complementary sequence to M13mp10w, but differed in the lengths of their non complementary 5' tail regions. Probes were synthesized to have a 3'-PO_4 instead of a 3'-OH to block any extension by Tag polymerase.

BW31 = 5' 5541-5512 3'
5'-*CGCTGCGCGTAACCACCACACCCGCCGCGCX-3'

BW33 = 5' 5541-5512 3'
5'-*gatCGCTGCGCGTAACCACCACACCCGCCGCCGCGCX-3'

BW35 = 5' 5541-5512 3'
5'-*cgtcaccgatCGCTGCGCGTAACCACCACACCCGCCGCGCX-3'

X = 3'-phosphate
a, t, g, c, = bases non-complementary to template strand
* = gamma ^{32}P-ATP label

For amplification of the 350 bp fragment, 10^{-3} pmol of target M13mp10w sequence were added to a 50 ul reaction volume containing 50 mM KCl, 10 mM Tris HCl pH 8.3, 3 mM $MgCl_2$, 10 pmol each of primers BW36 and BW42, 200 uM each of four deoxynucleoside triphosphates, 1.25 units Tag DNA polymerase and either 1, 10 or 20 pmol of isotopically diluted probe BW31, BW33 or BW35.

The amount of radiolabeled probe was held constant at 0.4 pmol per reaction and diluted to 1, 10 or 20 pmol with non-radioactive probe.

Tag polymerase was added as 4 ul per reaction at 0.3125 U/ul and diluted in 10 mM Tris-HCl pH 8.0, 50 mM KCl, 0.1 mM EDTA, 0.5% NP40+0.5% Tween 20, and 500 ug/ml gelatin.

A master reaction mix was made containing appropriate amounts of reaction buffer, nucleoside triphosphates, both primers and enzyme. From this master mix aliquots were taken and to them were added template and various concentrations of each probe. Control reactions consisted of adding all reaction components except template, and all reaction components except probe. Each reaction mixture was overlayed with 50 ul mineral oil to prevent evaporation, microcentrifuged for 45 seconds, and then placed into a thermal cycler. Reaction mixtures were subjected to the following amplification scheme:

Fifteen cycles:	96° C. denaturation, 1 min
	60° C. anneal/extension, 1.5 min
One cycle:	96° C. denaturation, 1 min
	60° C. anneal/extension, 5.5 min

After cycling, the mineral oil was extracted with 50 ul chloroform, the mixtures were stored at 4° C. and the following tests were performed.

C. Analysis

For acrylamide gel analysis, 4 ul of each amplification reaction were mixed with 3 ul 5X gel loading mix (0.125% bromophenol blue, 12.5% Ficoll 400 in H_2O) and loaded onto a 4% acrylamide gel (10 ml f 10X TBE buffer, 1 ml 10% ammonium persulfate, 10 ml 40% Bis Acrylamide 19:1, 50 ul TEMED, and 79 ml H_2O) in 1X TBE buffer (0.089M Tris, 0.089M boric

acid, and 2 mM EDTA) and electrophoresed for 90 min at 200 volts. After staining with ethidium bromide, DNA was visualized by UV fluorescence.

The results showed that the presence of each of these three probes at the various concentrations had no effect n the amount of amplified product generated. Sample lanes containing no probe showed discrete high intensity 350 base pair bands corresponding to the desired sequence. All lanes containing probe showed the same, as well as a few faint bands at slightly higher molecular weight. Control lanes without template added showed no bands whatsoever at 350 bases, only lower intensity bands representing primer at 30–40 bases.

After photographing, the gel was transferred onto Whatman paper, covered with Saran Wrap and autoradiographed. An overnight exposure revealed that 90–95% of the radiolabel was near the bottom of the gel, where probe or partially degraded probe would run.

For the denaturing gel analysis, 2 ul of each amplification reaction were mixed with 2 ul formamide loading buffer (0.2 ml 0.5M EDTA pH 8, 10 mg bromophenol blue, 10 mg xylene cyanol, 10 ml formamide), then heated to 96° C. for 3–5 min and placed on ice. Samples were loaded onto a 6.2% denaturing gradient polyacrylamide gel (7M urea with both a sucrose and a buffer gradient) according to the procedure of Sambrook et al., supra. The gel was electrophoresed for 90 min at 2000 V, 45 W, then transferred onto Whatman paper and autoradiographed.

Results from the denaturing gel indicated that about 50% of each probe was degraded into smaller labeled fragments. Approximately 50%–60% of the counts lie in the 30–40 base range, corresponding to undergraded probe. A very faint band is visible at 300 bases for all the amplification reactions, suggesting that a very small percentage of the probes have lost their $3'PO_4$ group and have been extended. The remainder of the counts are in the range of zero to fifteen bases. The resolution on such a gel does not reveal the exact size of products. This can be better noted by homochromatography analysis.

For a homochromatography analysis, 1 ul of each sample was spotted 1.2 cm apart onto a Polygram CEL 300 DEAE 20×20 cm cellulose thin layer plate, which was pre-spotted with 5 ul sheared herring sperm DNA (150 ug/ml) and allowed to dry. After the sample was dried, the plate was placed in a trough with distilled H_2O, and the water allowed to migrate just above the sample loading area. The plate was then placed in a glass development tank containing filtered Homo mix III (Jay et al., (1979) *Nuc Acids Res* 1(3):331–353), a solution of partially hydrolized RNA containing 7M urea, in a 70° C. oven.

The Homo-Mix was allowed to migrate by capillary action to the top of the plate, at which time the plate was removed, allowed to dry, covered with Saran Wrap, and then autoradiographed.

An overnight exposure of the homochromatography plate also indicated that about 40% of the probes were degraded into smaller fragments. These fragments were very specific in size, depending upon the length of the 5' non-complementary tail of each probe. FIG. 1 shows an autoradiograph of the TLC plate. Probe BW31 (Lanes 1–3) which was fully complementary to the M13mp10w template, generated labeled fragments predominantly one to two bases long. Probe BW33, (Lanes 4–6) containing a 5' 3 base non-complementary region, released products predominantly four to six bases long. BW35 (Lanes 7–9) had a 5' 10 base non-complementary tail and released products predominantly 12 to 13 bases in length. Lanes 10–12 are control reactions containing either BW31, BW33 or BW35 and all PCR components except template after 15 cycles. During DNA synthesis, the enzyme displaced the first ne or two paired bases it encountered and then cut at that site, indicative of an endonuclease-like activity. The results show specific probe release coordinately with product accumulation in PCR.

Example II: Specificity of Probe Label Release

The specificity of labeled probe release was examined by performing a PCR amplification using bacteriophage lambda DNA and primers, and a series of non-complementary kinased probes.

The region to be amplified was a 500 nucleotide region on whole bacteriophage lambda DNA from the GeneAmp ® DNA Amplification Reagent kit (Perkin-Elmer Cetus), flanked by primers PCRO1 and PCRO2, also from the GeneAmp ® DNA kit.

PCRO1 = 5' 7131–7155 3'
5'-GATGAGTTCGTGTCCGTACAACTGG-3'

PCRO2 = 5' 7630–7606 3';
5'-GGTTATCGAAATCAGCCACAGCGCC-3'

Aliquots of the same three labeled probes BW31, BW33 and BW35 identified in Example I, were used, all of which were entirely non-complementary to the target sequence.

For amplification of the 500 base pair region, 0.5 ng of target lambda DNA sequence (control Template, Lot #3269, 1 ug/ml, dilute 1:10 in 10 mM Tris-HCl pH 8.0, 1 mM EDTA, 10 mM NaCl for stock) were added to a 50 ul reaction volume containing 50 mM KCl, 10 mM Tris-HCl pH 8.3, 3 mM $MgCl_2$, 1 uM each of primers PCRO1 (Lot #3355) and PCRO2 (Lot #3268), 200 uM each of four deoxynucleoside triphosphates, 1.25 units Tag DNA polymerase, and either 2, 10 or 20 pmol of isotopically diluted probe BW31, BW33 or BW35.

The amount of radiolabeled probe was held constant to 0.4 pmol per reaction and diluted to 1, 10 or 20 pmol with non-radioactive probe.

Tag DNA polymerase was added as 4 ul per reaction at 0.3125 units/ul and diluted in 10 mM Tris-HCl pH 8.0, 50 mM KCl, 0.1 mM EDTA, 0.5% NP40+0.5% Tween 20, and 500 ug/ml gelatin.

The master reaction mix was made as previously taught, along with the control reactions minus probe or minus enzyme. The reaction mixtures were amplified following the cycling conditions set forth in Example 1B and then analyzed as follows.

For acrylamide gel analysis, 4 ul of each amplification reaction mixed with 3 ul 5X loading mix were loaded onto a 4% acrylamide gel in 1X TBE buffer and electrophoresed for 90 min at 200 volts. After staining with ethidium bromide, DNA was visualized by UV fluorescence.

The results show that the presence of any probe at any concentration has no effect on the amount of amplified product generated. Sample control lanes containing no probe, and all lanes containing probe, showed a discrete high intensity 500 base pair band corresponding to the desired sequence. Control lanes with no enzyme added did not show any product bands but only low

intensity bands representing primer and probe of approximately 30–40 nucleotides.

The homochromatography analysis provided in FIG. 2 shows an overnight exposure of the plate in which no degradation of the probes was observed. All of the counts were located at the point of origin, showing no release of labeled fragments. Lanes 1–3 are reactions containing probe BW31; Lanes 4–6 include probe BW33; Lanes 7–9 include probe BW35; and Lanes 10–12 are control reactions without template. This data show that the probe is not degraded unless specifically bound to target, and is able to physically withstand the PCR cycling conditions.

In the denaturing gel analysis, 2 ul of each amplification reaction were mixed with 2 ul formamide loading buffer (described in Example I) and placed on a heat block at 96° C. for 3–5 min. Samples were immediately placed on ice and loaded onto a 6.2% denaturing gradient acrylamide gel, and electrophoresed for 90 min at 2000 volts. After electrophoresis, the gel was transferred onto Whatman paper, covered with Saran Wrap and autoradiographed.

An overnight exposure revealed all of the counts in the 30–40 base pair range, corresponding to the sizes of the probes. Once again there was no probe degradation apparent, further confirming that probe must be specifically bound to template before any degradation can occur.

Example III: Specificity of Probe Label Release in the Presence of Genomic DNA

In this example, the specificity of probe label release was examined by performing a PCR amplification in the presence of degraded or non-degraded human genomic DNA.

The BW33 kinased probe used in this experiment had a specific activity of 5.28×10^6 cpm/pmol determined by TCA precipitation following the kinasing reaction. The region amplified was the 350 base pair region of M13mp10w, flanked by primers BW36 and BW42. Primer sequences and locations are listed in Example I. Human genomic DNA was from cell line HL60 and was used undergraded or degraded by shearing in a french press to an average size of 800 base pairs.

Each 50 ul amplification reaction consisted of 10^{-2} or 10^{-3} pmol of M13mp10w target sequence, 1 ug either degraded or non-degraded HL60 genomic DNA added to a mixture containing 50 mM KCl, 10 mM Tris HCl pH 8.3, 3 mM $MgCl_2$, 10 pmol each of primers BW36 and BW42, 200 uM each of four deoxynucleoside triphosphates, 1.25 units Tag DNA polymerase and 10 pmol of isotopically diluted probe BW33.

A master reaction mix was made containing appropriate amounts of reaction buffer, nucleoside triphosphates, primers, probe and enzyme. Aliquots were made and to them was added M13mp10w template and/or genomic DNA. Control reactions included all reaction components except M13mp10w target DNA, or all reaction components except genomic DNA.

Each reaction mixture was overlaid with 50 ul mineral oil, microcentrifuged and placed into a thermal cycler. Reaction mixtures were subjected to the following amplification scheme:

For 10, 15 or 20 cycles:	96° C. denaturation, 1 min
	60° C. anneal/extension, 1.5 min
Final cycle:	96° C. denaturation, 1 min
	60° C. anneal/extension, 5.5 min

After cycling, the mineral oil was extracted using 50 ul chloroform and samples were stored at 4° C.

Samples were subsequently analyzed by a 4% acrylamide gel electrophoresis, and homochromatography analysis.

For the acrylamide gel analysis, 4 ul of each reaction mixture were mixed with 3 ul 5X gel loading mix, loaded onto a 4% acrylamide gel in 1X TBE buffer, and electrophoresed for 90 min at 220 volts. DNA was visualized by UV fluorescence after staining with ethidium bromide.

In the lanes corresponding to control samples containing no M13mp10w target DNA, there were no visible product bands, indicating the absence of any cross-over contamination of M13mp10w. All subsequent lanes showed a band at 350 bases corresponding to the expected sequence. The intensity of the band was greater when 10^{-2} pmol M13mp10w target DNA was present over 10^{-3} pmol in the absence or presence of genomic DNA (degraded or undergraded). The product band intensity increased with increasing number of amplification cycles. Twenty cycles produced a band twice the intensity of that seen at ten cycles, and fifteen cycles generated a band of intermediate intensity. The amount of PCR product present varied on the amount of starting target template and the number of cycles, and the presence of 1 ug of human genomic DNA, whether degraded or undergraded, showed no effect at all on this product formation.

In the homochromatography analysis, 1 ul of each reaction mixture was spotted onto a DEAE thin layer plate, and placed in a developing chamber containing Homo-Mix III at 70° C. After 90 min, the plate was removed, allowed to dry, covered with Saran Wrap, and autoradiographed. An overnight exposure is shown in FIG. 3; in FIG. 3A, Lanes 1 to 6 show PCR reaction cycles in the absence of M13mp10w template DNA containing, alternately, degraded and undergraded HL60 DNA at 10, 15 and 20 cycles; and Lanes 7–12 are duplicate loading control reactions containing M13mp10w template DNA without any human genomic DNA at 10, 15 and 20 cycles. In FIG. 3B, reactions are amplified over increasing 5 cycle increments starting at 10 cycles. The M13mp10w template DNA concentration in the reactions shown in Lanes 1, 2, 5, 6, 9 and 10 is 10^{-2} pmol, while in lanes 3, 4, 7, 8, 11 and 12 is 10^{-3} pmol. The reactions shown in the odd numbered lanes from 1 through 1 contain degraded human genomic DNA and the even numbered lanes contain non-degraded human genomic DNA. Labeled probe fragments were seen as two well-defined spots migrating at approximately 4 and 5 bases in length on the thin layer plate. As the starting template concentration increased and/or as the cycle number increased, the amount of released labeled probe fragments also increased. The presence or absence of degraded or non degraded human genomic DNA did not interfere with or enhance probe hybridization and degradation.

The results show that increased amounts of released small probe fragments occur coordinately and simultaneously with specific product accumulation during the course of a PCR assay. The presence or absence of either a large amount of high complexity human genomic DNA or a large number of random DNA "ends"

has no effect on specific product accumulation or degree of probe release. Finally, the presence of a large amount of high complexity human genomic DNA does not lead to any detectable probe release in the absence of specific product accumulation.

Example IV: PCR with 3' Labeled Probe

A PCR amplification was performed which liberated a hybridized 3' radiolabeled probe into smaller fragments when the probe was annealed to template. The sequences of the probes were as follows:

DG46 = 5' 5541-5512-3'
5'-CGCTGCGCGTAACCACCACACCCGCCGCGC-3'

BW32 = 5' 5541-5512-3'
5'-gatCGCTGCGCGTAACCACCACACCCGCCGCGC-3'

BW34 = 5' 5541-5512-3'
5'-cgtcaccgatCGCTGCGCGTAACCACCACACCCGCCGCGC-3'

A. Labeling of Probes with ^{32}P-cordycepin and terminal transferase

Five pmol of each probe (DG46, BW32, BW34) were individually mixed with 17.4 units of terminal transferase (Stratagene) and 10 pmol cordycepin (cordycepin: 3'-deoxyadenosine-5'-triphosphate, New England Nuclear, 5000 Ci/mmol, diluted 3X with ddATP [Pharmacia]) in a 17.5 ul reaction volume containing 100 mM potassium cacodylate, 25 mM

Tris-HCl pH 7.6, 1 mM $CoCl_2$, and 0.2 mM dithiothreitol for 60 min at 37° C. The total volume was then phenol/chloroform extracted and ethanol precipitated. Probes were resuspended in 50 ul TE buffer and run over a Sephadex G-50 spin dialysis column according to the procedure of Sambrook, et al., Molecular Cloning, supra. The final concentration of probes was 0.1 pmol/ul. TCA precipitation of the reaction products indicated the following specific activities:

DG46: 2.13×10^6 *cpm/pmol*

BW32: 1.78×10^6 *cpm/pmol*

BW34: 5.02×10^6 *cpm/pmol*

Dentaturing gradient gel analysis comparison of the 3' radiolabeled probes to 5' kinased probes and BW35, show that the 3' radiolabeled probes ran in a similar fashion to the 5' radiolabeled probes.

Once again, the region amplified was the 350 base region on M13mp10w defined by primers BW36 and BW42. Primer sequences and locations are listed in Example I.

Each mixture consisted of adding 10^{-3} pmol of the target M13mp10w DNA to a 50 ul reaction volume containing 50 mM KCl, 10 mM Tris HCl pH 8.3, 3 mM $MgCl_2$, 10 pmol each of primers BW36 and BW42, 200 uM each of four deoxynucleoside triphosphates, 1.25 units of Tag DNA polymerase and either 2, 10, or 20 pmol of isotopically diluted probe DG46, BW32, or BW34.

A master reaction mix was made containing appropriate amounts of reaction buffer, nucleoside triphosphates, template and enzyme. Aliquots were made and to them was added the appropriate amount of primers and probes. Control reactions included all reaction components except primers, and all reaction components except probe.

Reaction mixtures were overlaid with 50 ul mineral oil, microcentrifuged and placed into a thermal cycler. Amplification scheme was as follows:

Fifteen cycles:	96° C. denaturation, 1 min
	60° C. anneal/extension, 1.5 min
Final cycle:	96° C. denaturation; 1 min
	60° C. anneal/extension, 5.5 min

After cycling, the mineral oil was extracted using 50 ul chloroform and samples were stored at 4° C.

Samples were analyzed by a 4% acrylamide gel, an 8% denaturing gradient acrylamide gel, and by homochromatography. For all three analyses, handling of reaction mixtures was as previously described.

In the 4% acrylamide gel analysis, a sharp band corresponding to the desired product at 350 bases was visible in all of the reaction mixtures except control reactions minus primers. In all of the reaction mixtures containing both primers and probe, a second band was visible at approximately 300 bases. This second band became more intense with increasing probe concentration, and probably corresponded to probe which was either not efficiently 3' radiolabeled or lost its 3' label, allowing probe extension to generate a second product.

An overnight exposure of the 8% denaturing gradient acrylamide gel showed a distribution of products ranging from full size probe down to less than 15 bases with all three probes being run. As would be expected, the 5'-3' nuclease activity of Tag DNA polymerase degraded the probe to a point where it was no longer stable and dissociated from the template.

The wide size distribution of products was illustrative of the continuously changing concentrations of reactants and temperature changes during PCR cycling. Such variations would lead to changes in annealing kinetics of probe and enzyme, allowing for probe to dissociate in a variety of sizes at different times in the cycling routine.

The homochromatography plate revealed the smallest product to be about 10 to 12 bases in length for all the probes examined. Since all three probes had identical sequence except at the 5' tail region, this result shows that for this particular probe sequence at an anneal/extend temperature of 60° C., the probe was degraded to about 10 bases and was then not stable enough to remain annealed to the template.

Example V: Polymerization Independent 5'-3' Nuclease Activity of Tag DNA Polymerase

Tag DNA polymerase was able to liberate the 5' ^{32}P-labeled end of a hybridized probe when positioned in the proximity of that probe by an upstream primer. A series f primers was designed to lie from zero to twenty bases upstream of hybridized kinased probe BW33.

BW37
Delta-0 5' 5571-5542 3'
5'-GCGCTAGGGCGCTGGCAAGTGTAGCGGTCA-3'

BW38
Delta-1 5' 5572-5543 3'
5'-GGCGCTAGGGCGCTGGCAAGTGTAGCGGTC-3'

BW39
Delta-2 5' 5573-5544 3'
5'-GGGCGCTAGGGCGCTGGCAAGTGTAGCGGT-3'

BW40
Delta-5 5' 5576-5547 3'
5'-AGCGGGCGCTAGGGCGCTGGCAAGTGTAGC-3'

BW41
Delta-10 5' 5581-5552 3'
5'-AAAGGAGCGGGCGCTAGGGCGCTGGCAAGT-3'

BW42
Delta-20 5' 5591-5562 3'
5'-GAAGAAAGCGAAAGGAGCGGGCGCTAGGGC-3'

About 0.5 pmol of probe BW33 and 0.5 pmol of one of each of the primers were annealed to 0.5 pmol M13mp10w in a 10.5 ul reaction volume containing 50 mM KCl, 10 mM Tris-HCl pH 8.3, and 3 mM $MgCl_2$. Control reaction mixtures contained either 20 uM or 200 uM each of four deoxynucleoside triphosphates. An additional primer, DG47, positioned 530 bases upstream from the probe was used.

DG47
Delta-530 5' 6041-6012 3'
5'-CGGCCAACGCGCGGGGAGAGGCGGTTTGCG-3'

Reaction mixtures were heated to 98° C. for 1 min and annealed at 60° C. for 30 min. Tubes were then microcentrifuged and placed in a water bath at 70° C. After ample time for reaction mixtures to equilibrate to temperature, 10, 5, 2.5, 1.25, or 0.3125 units of Tag DNA polymerase were added, and 4 ul aliquots were removed at 2, 5 and 10 min. Enzyme was inactivated by adding 4 ul 10 mM EDTA to each aliquot and placing at 4° C. Reaction mixtures were examined by homochromatography analysis.

In the homochromatography analysis, 1 ul of each sample was spotted onto DEAE cellulose thin layer plates and placed into a development chamber containing Homo-Mix III at 70° C. Homo-Mix was allowed to migrate to the top of each plate, at which time the plates were removed, dried, covered with Saran Wrap, and autoradiographed. FIG. 4 shows the results of this experiment.

In FIG. 4, Lanes 1 through 3 contain radiolabeled oligonucleotide molecular size markers of 6, 8, 9, 10, 11, 12 and 13 nucleotides. Lanes 4–10 show reactions for primers BW37, BW38, BW39, BW40, BW41, BW42 and DG47, respectively, in the absence of dNTP's. Lanes 11–24 show control reactions for all primers in the presence of 20 mM or 200 mM dNTP.

In the absence of dNTPs, Tag DNA polymerase generated labeled probe fragments using all of the primers with considerably less label being released as the primer-probe spacing increased. This effect was seen at all the enzyme concentrations examined (0.3125 U to 10 U/reaction) and all timepoints. The sizes of fragments released were the same, about two and three bases in length, however, the primary species varied depending upon which primer was added. The majority species released by the delta zero and delta two primers was one base smaller than that released by the delta one, five, ten, and twenty primers. This nuclease activity was polymerization-independent and proximity-dependent.

In the presence of nucleoside triphosphates, the sizes of labeled probe fragments released, and the relative proportions of each, were identical for all the primers examined. Also, the sizes of products were larger by one to two bases when dNTPs were present. It may be that while the enzyme was polymerizing, it had a "running start" and as it encountered hybridized probe, was simultaneously displacing one to two bases and then cutting, thus generating a larger fragment.

There was no detectable difference in amount of product released when dNTPs were at 20 uM or 200 uM each and no significant differences were seen due to extension times or enzyme concentrations in the presence of dNTPs.

Example VI: Example to Illustrate the Nature of Released Product Based on Probe Sequence at the 5' End

The effect of strong or weak base pairing at the 5' complimentary region of a probe on the size of released product was assessed. Two probes, BW50 and BW51, were designed to contain either a GC- or an AT-rich 5' complimentary region. BW50 and BW51 were compared to probe BW33 used in Example V.

BW50 =
5' 5521-5496 3'
5'-tatCCCGCCGCGCTTAATGCGCCGCTACA-3'

BW51 =
5' 5511-5481 3'
5'-gcaTTAATGCGCCGCTACAGGGCGCGTACTATGG-3'
a, t, g, c = bases which are non-complementary to template strand

BW50, BW51, and BW33 were labeled with ^{32}P-ATP using polynucleotide kinase and had the following specific activities:

BW50: 1.70×10^6 *cpm/pmol*

BW51: 2.22×10^6 cpm/pmol

BW33: 1.44×10^6 cpm/pmol

The final concentration of all three probes was 0.10 pmol/ul.

Individually, 0.5 pmol of either probe BW50, BW51, or BW33 and 0.5 pmol of primer BW42 were annealed to 0.5 pmol of M13mp10w in a 10.5 ul reaction volume containing 50 mM KCl, 10 mM Tris HCl, pH 8.3, 3 mM $MgCl_2$ and 200 uM each of four deoxynucleoside triphosphates. Control samples contained all reaction components except template. For the annealing step, reaction mixtures were heated to 98° C. for 1 min and annealed at 60° C. for 30 min. Tubes were then microcentrifuged and placed in a water bath at 50° C., 60° C., or 70° C. After ample time for reaction mixtures to equilibrate to temperature, 0.3125 units of Tag DNA polymerase was added. Four ul aliquots were removed at 1, 2, and 5 min. Reactions were inactivated by adding 4 ul of 10 mM EDTA to each aliquot and placing at 4° C. Samples were examined by homochromatography analysis and the results are shown in FIGS. 5 and 6.

FIG. 5 shows the reactions containing the 'GC'-rich probe BW50. Lanes 1–3 contain oligonucleotide molec-

ular size markers of 6, 8, 9, 10, 11, 12, and 13 nucleotides. Lanes 4–6 show extension reactions performed at 50° C. for 1, 2, and 5 minutes. Lanes 7–9 show extension reactions at 60° C. for 1, 2, and 5 minutes. Lanes 10–12 show reactions at 70° C. for 1, 2, and 5 minutes. Lanes 13–15 are control reactions containing all components except template, incubated at 70° C. for 1, 2 and 5 minutes.

FIG. 6 shows the reactions containing the 'AT' rich probe BW51. As in FIG. 5, Lanes 1–3 are oligonucleotide molecular size markers of 6, 8, 9, 10, 11, 12 and 13 nucleotides. Lanes 4–6 are extension reactions performed at 50° C. for 1, 2 and 5 minutes. Lanes 7–9 are reactions at 60° C. at 1, 2, and 5 minutes. Lanes 10–12 are reactions at 70° C. at 1, 2, and 5 minutes. Lanes 13–15 are control reactions containing all components except template, incubated at 70° C. for 1, 2 and 5 minutes.

The results demonstrate that the nature of probe label release was dependent on temperature and base composition at the 5' end. The more stable GC-rich probe BW50 showed little label release at 50° C. (FIG. 5, Lanes 4–6) and increasingly more at 60° FIG. 5, Lanes 7–9) and 70° C. (FIG. 5, Lanes 10–12 . The major products released were about 3–5 bases in length. BW51, which was AT-rich at the 5' end, showed as much label release at 50° C. (FIG. 6, Lanes 4–6) as was observed at the higher temperatures. In addition, the AT-rich probe generated larger-sized products than the GC-rich probe. Its base composition may give the opportunity for a greater "breathing" capacity, and thus allow for more probe displacement before cutting, and at lower temperatures than the GC-rich probe.

Example VII: HIV Capture Assay

The following is an example of the use of a dual labeled probe containing biotin in a PCR to detect the presence of a target sequence. Two oligonucleotides, BW73 and BW74, each complimentary to a portion of the HIV genome, were synthesized with a biotin molecule attached at their 3' ends. The 5' end of each oligonucleotide was additionally labeled with ^{32}P using polynucleotide kinase and ^{32}P-ATP. The two oligonucleotides PH7 and PH8 are also complimentary to the HIV genome, flank the region containing homology to the two probe oligonucleotides and can serve as PCR primers defining a 142 base product.

BW73 = ^{32}P-GAGACCATCAATGAGGAAGCTGCAGAATGGGAT-Y

BW74 = ^{32}P-gtgGAGACCATCAATGAGGAAGCTGCAGAATGGGAT-Y

PH7 = AGTGGGGGGACATCAAGCAGCCATGCAAAT

PH8 = TGCTATGTCAGTTCCCCTTGGTTCTCT

Y = biotin
lower case indicates bases which are non-complementary to template strand

A set of 50 ul polymerase chain reactions was constructed containing either BW73 or BW74, each doubly labeled, as probe oligonucleotides at 2 nM. Additionally, HIV template in the form of a plasmid clone was added at either 10^2 or 10^3 copies per reaction, and primer oligonucleotides PH7 and PH8 were added at 0.4 uM each. Tag polymerase was added at 1.25 U per reaction and dNTPs at 200 uM each. Each reaction was verlayed with 50 ul of oil, spun briefly in a microcentrifuge to collect all liquids to the bottom of the tube, and thermocycled between 95° C. and 60° C., pausing for 60 sec at each temperature, for 30, 35 or 40 cycles. At the conclusion of the thermocycling, each reaction was extracted with 50 ul of $CHCl_3$ and the aqueous phase collected.

Each reaction was analyzed for amplification by loading 3 ul onto a 5% acrylamide electrophoresis gel and examined for the expected 142 base pair product. Additionally, 1 ul of each reaction was examined by TLC homochromotography on DEAE cellulose plates. Finally, each reaction was further analyzed by contacting the remaining volume with 25 ul of a 10 mg/ml suspension of DYNABEADS M-280 streptavidin labeled, superparamagnetic, polystyrene beads. After reacting with the beads, the mixture was separated by filtration through a Costar Spin X centrifuge filter, the filtrate collected and the presence of released radiolabeled determined.

FIG. 7 contains images of the two gels used and shows that 142 base pair product occurs in all reactions, with and without probe, and FIG. 7 increases in amount both as starting template was increased from 10^2 to 10^3 copies and as thermocycling was continued from 30 to 35 and 40 cycles.

FIG. 8 is a composite of two autoradiographs of the TLC analysis of aliquots of the PCRs and show that radiolabel release occurs and increases in amount with both increases in starting template and with longer thermocycling. In the first TLC of PCRs using BW73, lanes 1 and 3 contain radiolabeled oligonucleotides 2 and 3 bases in length as size standards. Lanes 4, 5 and 6 contain samples from PCRs with 10^2 starting copies of template and lanes 7, 8 and 9 with 103 starting copies. Samples in lanes 4 and 7 were thermocycled for 30 cycles, in lanes 5 and 8 for 35 cycles and in lanes 6 and 9 for 40 cycles. In the second TLC of PCRs using BW74, lanes 1 and 2 are the radiolabeled 2 mer and 3 mer, lanes 4, 5 and 6 contain samples from PCRs with 10^2 starting copies of template thermocycled for 30, 35 and 40 cycles, respectively, and lanes 7, 8 and 9 with 10^3 copies of starting template thermocycled for 30, 35 and 40 cycles, respectively. The size of the released label is smaller with BW73 having no 5' non-complimentary bases as expected and larger with BW74 which has a 5' three base non-complimentary extension.

Each chromatogram was additionally analyzed by two dimensional radioisotope imaging using an Ambis counter. The results of Ambis counting and bead capture counting shown in Table 1. The good agreement in the two methods of measuring label release demonstrates the practicality of the use of labeled biotinylated probes and avidinylated beads in PCRs to determine product formation.

TABLE 1

	Number of Cycles	% of Label Released	
		Ambis	Capture
BW73			
10^2 copies	30	6.9	10.8

TABLE 1-continued

	Number of Cycles	% of Label Released	
		Ambis	Capture
	35	29.0	32.7
	40	47.2	47.2
10^3 copies	30	11.8	16.8
	35	35.6	39.3
	40	53.4	52.5
BW74			
10^2 copies	30	8.3	7.9
	35	20.7	25.2
	40	43.2	48.3
10^3 copies	30	15.7	14.7
	35	32	37.7
	40	46	47.9

Although the foregoing invention has been described in some detail for the purpose of illustration, it will be obvious that changes and modifications may be practiced within the scope of the appended claims by those of ordinary skill in the art.

We claim:

1. A process for the detection of a target nucleic acid sequence in a sample, said process comprising:

(a) contacting a sample comprising single-stranded nucleic acids with an oligonucleotide containing a sequence complementary to a region of the target nucleic acid and a labeled oligonucleotide containing a sequence complementary to a second region of the same target nucleic acid sequence strand, but not including the nucleic acid sequence defined by the first oligonucleotide, to create a mixture of duplexes during hybridization conditions, wherein the duplexes comprise the target nucleic acid annealed to the first oligonucleotide and to the labeled oligonucleotide such that the 3' end of the first oligonucleotide is upstream of the 5' end of the labeled oligonucleotide;

(b) maintaining the mixture of step (a) with a template-dependent nucleic acid polymerase having a 5' to 3' nuclease activity under conditions sufficient to permit the 5' to 3' nuclease activity of the polymerase to cleave the annealed, labeled oligonucleotide and release labeled fragments; and

(c) detecting and/or measuring the release of labeled fragments.

2. The process of claim 1 wherein the 3' end of the first oligonucleotide in the annealed duplex of step (a) is within about 20 nucleotides of the 5' end of an annealed, labeled oligonucleotide, thereby having spacing effective to permit the release of labeled fragments in the absence of nucleic acid polymerization.

3. The process of claim 1 wherein the oligonucleotides comprise deoxyribonucleotides.

4. The process of claim 1 wherein the nucleic acid polymerase is a DNA polymerase having a 5' to 3' nuclease activity.

5. The process of claim 1 wherein a nucleotide within the label oligonucleotide is modified to control nuclease cleavage specificity.

6. The process of claim 1 wherein said labeled oligonucleotide comprises at least one label.

7. The process of claim 1 wherein the labeled oligonucleotide comprises first and second labels wherein the first label is separated from the second label by a nuclease susceptible cleavage site.

8. The process f claim 6 wherein the labeled ligonucleotide is labeled at the 5' terminus.

9. The process of claim 7 wherein the labeled oligonucleotide further comprises a tail of non-nucleic acids or a sequence of nucleotides which is non-complementary to the target nucleic acid sequence.

10. The process of claim 9 wherein the label is attached to a nucleotide in the tail or non-complementary sequence.

11. The process of claim 10 wherein the label is at the 5' terminus and is separated from the sequence complementary to the target nucleic acid sequence by the tail or non complementary sequence.

12. The process of claim 1 performed under conditions sufficient to promote nucleic acid polymerization, wherein the release of labeled fragments occurs during extension of the first oligonucleotide.

13. A polymerase chain reaction (PCR) amplification process for detecting a target nucleic acid sequence in a sample, said process comprising:

(a) providing to a PCR assay containing said sample, at least one labeled oligonucleotide containing a sequence complementary to a region of the target nucleic acid, wherein said labeled oligonucleotide anneals within the target nucleic acid sequence bounded by the oligonucleotide primers of step (b);

(b) providing a set of oligonucleotide primers, wherein a first primer contains a sequence complementary to a region in one strand of the target nucleic acid sequence and primes the synthesis of a complementary DNA strand, and a second primer contains a sequence complementary to a region in a second strand of the target nucleic acid sequence and primes the synthesis of a complementary DNA strand; and wherein each oligonucleotide primer is selected to anneal to its complementary template upstream of any labeled oligonucleotide annealed to the same nucleic acid strand;

(c) amplifying the target nucleic acid sequence employing a nucleic acid polymerase having 5' to 3' nuclease activity as a template-dependent polymerizing agent under conditions which are permissive for PCR cycling steps of (i) annealing of primers and labeled oligonucleotide to a template nucleic acid sequence contained within the target sequence, and (ii) extending the primer wherein said nucleic acid polymerase synthesizes a primer extension product while the 5' to 3' nuclease activity of the nucleic acid polymerase simultaneously releases labeled fragments from the annealed duplexes comprising labeled oligonucleotide and its complementary template nucleic acid sequences, thereby creating detectable labeled fragments; and

(d) detecting and/or measuring the release of labeled fragments to determine the presence or absence of the target sequence in the sample.

14. The PCR process of claim 13 wherein said nucleic acid polymerase is a thermostable enzyme.

15. The PCR process of claim 14 wherein said thermostable enzyme is the DNA polymerase from a Thermus species.

16. The PCR process of claim 13 wherein the 3' end of an annealed oligonucleotide primer is within about 20 nucleotides the 5' end of the labeled oligonucleotide annealed to the same nucleic acid strand.

17. The PCR process of claim 16 wherein said labeled oligonucleotide has a blocked 3' terminus to prevent extension by the nucleic acid polymerase.

18. The PCR process of claim 16 wherein the labeled oligonucleotide further comprises a sequence of one to

about ten nucleotides which sequence is substantially non-complementary to the target nucleic acid sequence.

19. The PCR process of claim 13 wherein the labeled oligonucleotide comprises first and second labels wherein the first label is separated from the second label by a nuclease susceptible cleavage site.

20. The PCR process of claim 13 wherein a pair of labeled oligonucleotides probes are provided in step (a).

21. The PCR process of claim 20 wherein said pair of labeled probes anneal to different, non-overlapping regions of the same complementary nucleic acid strand, wherein the 5' end of the second labeled probe is adjacent the 3' end of the first labeled probe.

22. The PCR process of claim 18 wherein the label is attached to a nucleotide in the non complementary sequence.

23. The PCR process of claim 22 wherein the label is at the 5' terminus and is separated from the complementary probe sequence by the non-complementary sequence.

24. The PCR process of claim 13 wherein the oligonucleotide is labeled at the 5' terminus.

25. The PCR process of claim 17 wherein the oligonucleotide is labeled at the blocked 3' terminus.

26. The PCR process of claim 13 wherein the label is attached to an internal sequence of the oligonucleotide.

27. The PCR process of claim 13 wherein the label provides a signal proportional to the number of target nucleic acid sequences amplified.

28. The PCR process of claim 13 wherein the label is a deoxyribonucleoside analog having signal-generating properties.

29. The PCR process of claim 13 wherein the labeled oligonucleotide comprises a pair of interactive signal-generating labels effectively positioned on the oligonucleotide to quench the generation of detectable signal, said labels being separated by a site within the oligonucleotide susceptible to nuclease cleavage, thereby allowing, during primer extension, the 5' to 3' nuclease activity of the nucleic acid polymerase to separate the first interactive signal generating label from the second interactive signal generating label by cleaving at the susceptible site thereby yielding a detectable signal.

30. The PCR process of claim 29 wherein said first label is a chemiluminescent substrate and said second label is a fluorophore which interacts therewith.

31. The PCR process of claim 13 wherein the label of said oligonucleotide is attached through a spacer arm of sufficient length to permit the 5' to 3' nuclease activity of the nucleic acid polymerase to release labeled fragments.

32. The PCR process of claim 13 wherein the melting temperature (T_m) differential between the labeled oligonucleotide and its' associated upstream oligonucleotide primer is effective to provide preferential binding of the labeled oligonucleotide during the annealing step of PCR cycles.

33. The PCR process of claim 32 wherein the T_m of the labeled oligonucleotide is as great as 40° C. higher than the T_m of the upstream oligonucleotide primer.

34. The PCR process of claim 13 wherein the labeled oligonucleotide fragments comprise a mixture of mono-, di and larger nucleotide fragments.

35. The PCR process of claim 13 which further comprises separating labeled oligonucleotide fragments from other components in the PCR mixture prior to detection of labeled fragments.

36. The PCR process of claim 35 wherein the separation step uses size exclusion chromatography.

37. The PCR process of claim 35 wherein the labeled fragments are separated from the PCR mixture by solid phase extraction.

38. The PCR process of 37 wherein avidin or streptavidin is attached to the solid phase and the labeled oligonucleotide further comprises a bound biotin molecule separated from the label by a nuclease susceptible cleavage site.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 5,210,015

DATED : May 11, 1993

INVENTOR(S) : David H. Gelfand, Pamela M. Holland, Randall K. Saiki, and Robert M. Watson

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 20, line 62, please delete "Tag" and insert therefor --Taq--.

Column 20, line 63, please delete "Tag" and insert therefor --Taq--.

Column 21, line 38, please delete "Tag" and insert therefor --Taq--.

Column 21, line 59, please delete "Tag" and insert therefor --Taq--.

Column 22, line 61, please delete "Tag" and insert therefor --Taq--.

Column 23, line 63, please delete "Tag" and insert therefor --Taq--.

Column 24, line 31, please delete "103" and insert therefor --10^3--.

Column 27, Claim 22, line 2, please delete "non complementary" and insert therefor --non-complementary--.

Signed and Sealed this

Nineteenth Day of July, 1994

Attest:

BRUCE LEHMAN

Attesting Officer

Commissioner of Patents and Trademarks